Supreme Court, U.S.
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IN THE

Supreme Court of the United States

ORMCO CORPORATION,
Petitioner,

v.

ALIGN TECHNOLOGY, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a court can properly determine an inventor's rights under a patent without regard to the text of the claims in the patent.

PARTIES TO THE PROCEEDINGS

Pursuant to Rule 14.1(b), the following list identifies all of the parties appearing here and before the Court of Appeals for the Federal Circuit.

The petitioner here and appellant and cross-appellee below is Ormco Corporation. Allesee Orthodontic Appliances, Inc. appeared below as a cross-appellee.

The respondent here and appellee and cross-appellant below is Align Technology, Inc.

RULE 29.6 STATEMENT

Ormco Corporation is the parent company of Allesee Orthodontic Appliances, Inc. Ormco Corporation is a wholly owned subsidiary of Sybron Dental Specialties, Inc. Sybron Dental Specialties Inc. is a wholly owned subsidiary of Danaher Corporation, a publicly traded corporation. No other publicly held company owns 10% or more of the stock of any of those companies.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDINGS	ii
RULE 29.6 STATEMENT	ii
TABLE OF AUTHORITIES	vi
OPINIONS BELOW	1
JURISDICTION	2
STATUTORY PROVISIONS INVOLVED	2
STATEMENT OF CASE	2
A. The district court determined non-infringement and invalidity without construing the claims	4
B. The Federal Circuit affirmed without construing a single word in any claim	5
REASONS FOR GRANTING THE PETITION	9
I. THE FEDERAL CIRCUIT'S DISREGARD OF THE TEXT OF THE CLAIMS IS IN DIRECT CONFLICT WITH THIS COURT'S PRECEDENTS AND EVISCERATES THE PUBLIC NOTICE FUNCTION OF THE PATENT'S CLAIM LANGUAGE	12
II. THE CONFLICT IS ONGOING AS FEDERAL CIRCUIT PANELS ARE SPLIT ON THIS ISSUE AND THE FEDERAL CIRCUIT HAS PROVED UNABLE OR UNWILLING TO RESOLVE THIS FUNDAMENTAL AND RECURRING PROBLEM	18

TABLE OF CONTENTS—Continued

Page

III. THE COURT SHOULD FINALLY RESOLVE THIS RECURRING CONFLICT THAT UNDERMINES CONGRESS'S POLICY DECISION TO PROTECT INTELLECTUAL PROPERTY RIGHTS THROUGH PATENT LAW..... 23

CONCLUSION 26

APPENDIX A: OPINION AND JUDGMENT FROM THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT.... 1a

APPENDIX B: ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT, DEFENDANT'S MOTION TO LIMIT CLAIMS, AND PLAINTIFF'S MOTION FOR A MARKMAN DETERMINATION FROM THE U.S. DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA SOUTHERN DIVISION..... 40a

APPENDIX C: ORDER DENYING PANEL REHEARING AND PETITION FOR REHEARING EN BANC FROM THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT 55a

APPENDIX D: STIPULATION AND FINAL JUDGMENT FROM THE U.S. DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA WESTERN DIVISION..... 57a

APPENDIX E: CLAIMS OF UNITED STATES PATENT NO. 6,616,444..... 63a

TABLE OF CONTENTS—Continued

Page

APPENDIX F: PAGES 45 AND 46 FROM ALIGN TECHNOLOGY, INC.'S APPEAL BRIEF FILED AUGUST 4, 2006 ..... 78a

APPENDIX G: ALIGN TECHNOLOGY, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT FILED FEBRUARY 12, 2004, PAGE 7, ALSO CONTAINED AT A02217 IN THE FEDERAL CIRCUIT JOINT APPENDIX 80a

APPENDIX H: MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION OF ALIGN TECHNOLOGY, INC. FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT FILED JANUARY 22, 2004, PAGE 16, ALSO CONTAINED AT A00738 IN THE FEDERAL CIRCUIT JOINT APPENDIX 82a

TABLE OF AUTHORITIES

FEDERAL CASES Page

Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361 (Fed. Cir. 2003) 20
Altiris, Inc. v. Symantec Corp., 318 F.3d 1363 (Fed. Cir. 2003) 20
Altoona Publix Theatres v. Am. Tri-Ergon Corp., 294 U.S. 477 (1935).....2, 3, 9, 12, 14
Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961) 12, 15
Barnhart v. Sigmon Coal Co., 534 U.S. 438 (2002)..... 16
Bonito Boats Inc. v. Thunder Craft Boats Inc., 489 U.S. 141 (1989)..... 13, 23
Cargill, Inc. v. Sears Petroleum & Transport Corp., 2004 WL 3507329 (N.D.N.Y. Aug. 27, 2004) 25
Cultor Corp. v. A.E. Staley Mfg., 224 F.3d 1328 (Fed. Cir. 2000) 20
Desert Palace, Inc. v. Costa, 539 U.S. 90 (2003)..... 16
Dolan v. U.S. Postal Serv., 546 U.S. 481 (2006)..... 16
Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002).....2, 11, 13, 23
Florida Power & Light Co. v. Lorion, 470 U.S. 729 (1985)..... 16
Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 527 U.S. 627 (1999)..... 19
Graver Tank & Mfg. Co. v. Linde Air Products Co., 336 U.S. 271 (1949)..... 13, 14

TABLE OF AUTHORITIES—Continued

Page

Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605 (1950) 13, 14
Harris Corp. v. Ericsson Inc., 417 F.3d 1241 (Fed. Cir. 2005) 24
Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111 (Fed. Cir. 2004) 19
Keystone Bridge Co. v. Phoenix Iron Co., 95 U.S. 274 (1877) 24
Knight v. C.I.R., 128 S.Ct. 782 (2008) 16
Koons Buick Pontiac GMC, Inc. v. Nigh, 543 U.S. 50 (2004) 16
Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) 7
Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) 3, 6, 9, 10, 12, 19
Merck & Co., Inc. v. Teva Pharma. USA, Inc., 395 F.3d 1364 (Fed. Cir. 2005) 25
Merrill v. Yeomans, 94 U.S. 568 (1876) 14
Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473 (Fed. Cir. 1998) 22
Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) 21, 22
Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243 (Fed. Cir. 1998) 19
Smith v. Snow, 294 U.S. 1 (1935) 9, 14, 15
Toro Co. v. White Consol. Indus., 199 F.3d 1295 (Fed. Cir. 1999) 20
Ultratech, Inc. v. Tamarak Scientific Co., 2005 WL 2562623 (N.D. Cal. Oct. 11, 2005) 25

TABLE OF AUTHORITIES—Continued

Page

United States v. Gonzales, 520 U.S. 1 (1997) 16
United States v. Hohri, 482 U.S. 64 (1987) .. 19
United Steelworkers v. Weber, 443 U.S. 193 (1979) 16
Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860 (Fed. Cir. 1997) 19
Ventana Medical Sys. v. Biogenex Labs., 473 F.3d 1173 (Fed. Cir. 2006) 11, 18, 23
Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997) 3, 9, 13
White v. Dunbar, 119 U.S. 47 (1886) 15
York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568 (Fed. Cir. 1996) 19

CONSTITUTIONAL PROVISIONS

U.S. Const. Art. I, § 8, cl. 8 13

FEDERAL STATUTES

35 U.S.C. § 102 12
35 U.S.C. § 103 12
35 U.S.C. § 112 .....2, 9, 12, 15
35 U.S.C. § 271(a) 13
28 U.S.C. § 1254(1) 2
28 U.S.C. § 1338(a) 4

ARTICLES

William N. Eskridge, Jr., *The New Textualism*, 37 UCLA L. Rev. 621 (1990) 16

TABLE OF AUTHORITIES—Continued

Page

Kimberly Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 Lewis & Clark L. Rev. 231 (2005) 21

Gerson Panitch, *Is the Name of the Game Still the Claim? The Post-Phillips Revolution in Patent Law*, Intellectual Property Today, June 2007 22

R. Polk Wagner & Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. Pa. L. Rev. 1105 (2004) 20

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Ormco Corp. respectfully requests that this Court grant the petition for a writ of certiorari to review the decision and judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The decision of the court of appeals (Appendix ("App.") 1a-39a) is published at 498 F.3d 1307 (Fed. Cir. 2007). The order of that court denying the Petition for Panel Rehearing and Rehearing en Banc (App. 55a-56a) was entered on October 24, 2007 and is unreported. The opinion of the United States District Court for the Central District of California (App. 40a-54a) granting summary judgment of non-infringement is unreported.

JURISDICTION

The court of appeals entered its judgment on August 24, 2007, and denied the petition for rehearing on October 24, 2007. On January 7, 2008, the Chief Justice granted an extension of time within which to file a petition for certiorari to and including February 14, 2008. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 112 provides in relevant part: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

STATEMENT OF THE CASE

It is axiomatic that in all cases of statutory construction, the starting point is the text of the statute. That is because the text reflects Congress's intent. An equally fundamental and analogous rule exists in patent law: in construing the claims of a patent—that portion of the patent that defines the invention—the starting point must be the text of the claims. Both the Patent Act (35 U.S.C. § 112) and this Court's precedents expressly provide that the patented invention is defined by the patent's claims. *Altoona Publix Theatres v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935) ("Under the statute, it is the claims of the patent which define the invention."). Thus, the patent claims, similar to the text of a deed, serves an important public notice function: informing the public which products or processes would infringe the patent and which would not. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535

U.S. 722, 730-31 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33-34 (1997) (claims serve definitional and notice function). "Victory in an infringement suit requires a finding that the patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim mean.'" *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996).

The Federal Circuit here defined the patented invention without regard to the claims and without ever determining what any of the words in the 92 asserted claims mean. In fact, the court ignored most of the 92 claims.[1] Instead of looking to the text of the claims, the Federal Circuit, as the dissent pointed out, gleaned the purported "invention" from sources other than the claim language and then compared that finding—not the claims—to the product accused of infringement. Only by departing from this Court's precedent and ignoring the text of the claims could the Federal Circuit hold that "the invention" involves an automatic determination of finish tooth positions *without operator involvement* when the claim expressly requires "*an operator* interacting with a computer . . . , altering the graphic representation [of the teeth] . . . to produce a digital model of a desired arrangement of the teeth. . . ." App. 63a (claim 1, Pat. No. 6,616,444 (the "'444 patent")). The Federal Circuit's holding that "the invention" can be defined from sources other than the claims eviscerates the public notice function of the patent laws and will foment further confusion and unpredictability on *the*

[1] Each claim stands on its own as defining an invention independent of the other claims. *Altoona Publix Theatres*, 365 U.S. at 487.

fundamental issue presented by every patent—what is the patented invention? The direct conflict between the Federal Circuit and this Court on an issue as important as the role of text in patent claim construction clearly warrants certiorari.

A. The district court determined non-infringement and invalidity without construing the claims.

Ormco sued respondent Align for infringing 92 claims in four patents. Most of the asserted claims are found in the '444 patent. The claims relate to the use of computers to assist orthodontists in the design and manufacture of custom orthodontic appliances, *i.e.*, appliances based upon the individual patient's anatomy. App. 63a-77a. Respondent Align designs and manufactures custom orthodontic appliances using a computer to alter images of the patient's teeth to arrange them in various desired positions. App. 49a-50a. The district court had jurisdiction under 28 U.S.C. § 1338(a).

Respondent moved the district court for summary judgment of non-infringement, arguing that all 92 of the asserted claims were limited to "automatic computer determination of the finish positions of teeth." App. 44a. According to respondent, it did not infringe because its process uses "skilled operators rather than a fully automated computerized process to determine finish positions of the teeth." App. 17a. Respondent identified nothing in the text of '444 patent claim 1, however, or in the text of any of the other 92 asserted claims, that required Ormco's invention to be limited in this way. Instead, respondent pressed the district court categorically not to review the claims at all, arguing that "the

claims need not be individually discussed"; that "there is no need . . . to review each and every asserted claim"; and that the "issue is not the meaning of a particular word, but rather that Ormco made it perfectly clear that *the very nature of its invention* was for automatic computer determination of the finish positions of teeth. . . ." App. 80a; App. 82a-83a.

The district court accepted this curious methodology, stating that it was "not interpreting the specific language of the claims to favor one side or the other." App. 42a n.1. It granted summary judgment of no infringement by holding that Ormco's invention required automatic determination of finish tooth positions and denied as moot Ormco's motion for briefing and a hearing on the meaning of particular claim terms. App. 42a n.1 and App. 49a-52a. Having thus determined the content of Ormco's patented invention without regard to the claims, the district court subsequently granted respondent summary judgment that all the claims were invalid as not enabled.

B. The Federal Circuit affirmed without construing a single word in any claim.

A divided panel of the Federal Circuit affirmed the district court's judgment with respect to almost all of the 92 asserted claims.[2] Some Federal Circuit cases hold that when a district court refused to construe the language of a claim, the proper course for the

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[2] The court excepted claims 37-40, 45, and 69 of the '444 patent. In its appeal brief, respondent stated that these six claims "on their face stop short of any aspect of the essence of the invention," and thus were "the only claims that could survive this appeal." App. 78a-79a.

court of appeals is to remand to require the district court to perform its claim construction function in accordance with *Markman*, 517 U.S. at 389-91. App. 25a-26a. Indeed, the dissent here concluded that since there was no claim construction record developed below, "the district court's failure to construe the claim language in this case, standing alone, warrants remand." App. 27a.

The majority did not follow this precedent. It held instead that because it reviews "decisions, not opinions," it "need not exalt form over substance and vacate what is essentially a correct decision." App. 18a. The majority held that Ormco's invention was "automatic computer determination of the finish positions of the teeth without human adjustment of the final results." App. 17a. Based on that holding, the court then found that these claims were not infringed. *Id.* It also found these claims were invalid because "Ormco had never attempted to create a computerized system that automatically determined tooth positions without human decision making." App. 19a.

In reaching its conclusion, the majority did not cite or begin with the text of any of the claims it purported to construe. App. 28a. Instead, the court began its analysis with the patents' lengthy and complex common specification, concluding: "[t]he specification thus provides clear indication that *the invention* is in the automatic determination of tooth position." App. 10a (emphasis added).

Having divined the "patented invention" from the specification alone, without recourse to the text of the claims, the court then equivocated, conceding that the specification "standing alone, may not be conclusive in showing that the claims require completely

automatic determination of final tooth positions." App. 10a. To quote the dissent: "[R]ecognizing the danger of counseling a district court to rely on language from the specification *to the exclusion* of language in the claims themselves, and recognizing that the statements in the specifications are less definitive than Align claims, the majority concedes that . . . the specification may not be conclusive to show that the claims require completely 'automatic determination of finish tooth positions.'" App. 33a (emphasis added). That should have been reason enough to remand to the district court to construe the claims.

Undaunted and in further disregard of the claim text, the court of appeals sought to bolster its conclusion by turning to the prosecution history of a patent other than one in litigation, *viz.* the history of the '562 patent.[3] The '562 patent is a distant ancestor to the '444 patent. The claims of the '562 patent are not at issue in this case and, as the dissent correctly observed, "do not share claim language with the majority of the claims at issue in this suit." App. 34a. Simply stated, the court ignored the prosecution history of the claims of the '444 patent. App. 37a. n.5.

As summarized by the dissent: "[A]fter examining the specification of one of the patents in suit (but not its prosecution history), and the prosecution history of a patent which is not in suit, [the majority] back[ed] into a form of claim construction by asserting that all of the claims address themselves to

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[3] A prosecution history is the Patent Office record of the patent application and the proceedings that lead to an issued patent. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996).

the practice of determining finish tooth positions." App. 28a. The majority never identified any "word or words in the claims in suit it purport[ed] to construe," and never identified "*what* language is used in *which* claims to describe that practice, or why such language is in need of interpretation." App. 28a. (emphasis in original). Of the 92 claims asserted, the court failed even to mention any language from 55 of the claims asserted from the '444 patent—independent claims 10, 23, 30, 46, 54, and 70 and claims that depend from them—and ignored their prosecution history.

The dissent, by Judge O'Malley, was highly critical of the majority. She pointed out that the majority "concede[d], as it must, that none of the claims in suit 'expressly recite automatic control of the finish tooth positioning.'" App. 28a (quoting majority). Nevertheless, "[d]espite the absence of this language in the claims . . . the [majority] concludes that this unstated (and seemingly important) limitation is 'what [the claims] mean.'" App. 28a (quoting majority).

> [T]he majority has: imported the terms "automatically" and "automated" from the specification to the claims; found that the terms "automatically" and "automated," when used in the specification, are the same terms (without a record of how one skilled in the art would construe those terms); concluded that, in every instance, the words "automatically" and "automated" mean "completely automatically" or "completely automated;' found that, where a claim is silent on the issue, use of an operator is wholly precluded; and found that, where involvement of an operator is claimed, that operator cannot be skilled.

App. 32a. Accordingly, the dissent would have reversed and remanded "with direction that the claim language at issue *be construed* and that a record supporting that construction be developed." App. 39a (emphasis added).

REASONS FOR GRANTING THE PETITION

The Federal Circuit's holding renders meaningless 35 U.S.C. § 112's express direction that the claims define the patented invention. It also conflicts directly with this Court's controlling precedent that "[u]nder the statute, it is the claims of the patent which define the invention." *Altoona Publix Theatres*, 294 U.S. at 487. "[T]he claims of the patent, not its specifications, measure the invention." *Smith v. Snow*, 294 U.S. 1, 11 (1935); *see also Warner-Jenkinson*, 520 U.S. at 29 ("[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention" (discussing doctrine of equivalents)).

Claim construction is the foundation for judging patent infringement and patentability. Infringement "necessitates a determination of 'what the words in the claim mean.'" *Markman*, 517 U.S. at 374. Clearly delineating the boundaries of the patented property rights by adhering to the claim text is vital to providing the public with notice of what is patented. Failure to define the patentee's rights by reference to the patent claims destroys the ability of the public, and the patent owner, to know what is owned. In this case, the Federal Circuit held that the essence of "the invention" could be determined from sources other than the patents' claims; indeed, the court of appeals ignored over half of the claims at issue in this case and, as the dissent pointed out,

never identified "*what* language is used in *which* claims to describe that practice, or why such language is in need of interpretation." App. 28a.

This case also poses sharply the conflict within the Federal Circuit, which has become increasingly polarized, concerning the primacy to be accorded to the actual language of the claims. Since this Court in *Markman* assigned the task of claim construction to judges in the hope of increased uniformity, 517 U.S. at 390, the binding law from the Federal Circuit on claim construction has become increasingly confused and varies by panel with unpredictable results. Some Federal Circuit panels look first to the text of the claim and anchor the claim construction analysis to specific language in the claim to define the patented invention; other Federal Circuit panels are decidedly more free-form, determining claim scope by picking and choosing from among various types of statements in the specification and prosecution history with little or no regard for the actual language of the claims. The majority opinion here presents a stark example of this latter, atextual, approach.

By analogy to statutory interpretation, it is as if some Federal Circuit decisions accord primary importance to the text of the statute that is at issue, while other Federal Circuit decisions focus primarily on the statute's legislative history and overall purpose. This Court long ago resolved the proper methodology for deciding this question in the context of statutory interpretation—the process begins and often ends with the text and only when there is ambiguity does the Court look to other sources. The function of those other sources, moreover, is simply to shed light on the correct meaning of the statutory text—not to rewrite the statute so that it effectively

says something else. The Court should follow the same course here and make clear that claim construction can never be divorced from the language of the claims. The claim language always should be the starting point and often the end point of the inquiry, but it should never be an afterthought.

The difference in approach within the Federal Circuit, as exemplified by this case, can often depend on a single judge on the panel. In *Ventana Medical Sys. v. Biogenex Labs.*, 473 F.3d 1173 (Fed. Cir. 2006), the majority adhered to the claim text, while the dissent expressly advocated an atextual "essence of the invention" approach; the Federal Circuit's decision in this case is actually the *dissent* in *Ventana*, creating directly conflicting standards that can only bewilder both litigants and district courts. *Id.* at 1185-87.

The Court should intervene now because the Federal Circuit has made it clear that it either is unwilling or unable to halt the growing disparity in its precedent. This confusion on an issue central to every patent, and to every patent case, has allowed district courts to "streamline" the claim construction process in a way that does violence to the text of the claims and in turn renders the public notice function a nullity. The patent laws reflect a policy decision that intellectual property protection through patent rights has a strong positive effect on technological change and therefore on economic growth. Achieving these benefits, however, requires that the boundaries of the patent right be clear. "A patent owner should know what he owns, and the public should know what he does not," and "[t]his clarity is essential to promote progress, because it enables efficient investment in innovation." *Festo*, 535 U.S. at 730-31.

The Federal Circuit's failure to provide a uniform rule of law on the role of the claim text in defining the scope of the patented invention yields unpredictable results that subvert that national policy decision. That is reason enough for the Court to grant certiorari.

I. THE FEDERAL CIRCUIT'S DISREGARD OF THE TEXT OF THE CLAIMS IS IN DIRECT CONFLICT WITH THIS COURT'S PRECEDENTS AND EVISCERATES THE PUBLIC NOTICE FUNCTION OF THE PATENT'S CLAIM LANGUAGE.

The Federal Circuit here determined "the invention" in the four patents in suit by attempting to discern "the invention" from the very lengthy specification and the prosecution history of a patent not even in suit, rather than from the text of the claims. Its decision directly conflicts with *the* fundamental tenet of patent law that a patented invention's scope is determined by the text of the claims. 35 U.S.C. § 112; *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("the claims made in the patent are the sole measure of the grant"); *Altoona Publix Theatres*, 294 U.S. at 487 ("Under the statute, it is the claims of the patent which define the invention."). Section 112 of the patent statute requires that every patent contain one or more claims "particularly point out and distinctly claiming" the subject matter of the invention. 35 U.S.C. 112, ¶ 2. The patent claim thus defines the invention for the purpose of applying the conditions of patentability under the patent statutes. *See generally* 35 U.S.C. §§ 102-103 & 112. The patent claim is the measure by which patent infringement and patent invalidity is judged. *Markman*, 517 U.S.

at 374; *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 336 U.S. 271, 276-78 (1949). The patent claim gives the public notice of what is, and what is not, the "patented invention" that persons cannot make, use or sell without incurring liability to the patent owner. 35 U.S.C. § 271(a).

This public notice function of patent claims is critical to achieving the policy aims of Congress. The patent system embodies "a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats Inc. v. Thunder Craft Boats Inc.*, 489 U.S. 141, 150-51 (1989). In *Festo* this Court observed:

> The patent laws "promote the Progress of Science and the useful Arts" by rewarding innovation with a temporary monopoly. U.S. Const. Art. I, § 8, cl. 8. The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not.

535 U.S. at 730-31.

In furtherance of the public notice function, the infringement inquiry requires attention to each claim element rather than the invention as a whole. *See e.g. Warner-Jenkinson Co.*, 520 U.S. at 29; *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950) ("In determining whether an accused device or composition infringes a valid patent, resort must be had in the first instance to the words of the

claim. If accused matter falls clearly within the claim, infringement is made out and that is the end of it."). The issue is whether the accused product or process falls within the description of the claim, not whether it is the same or similar to an embodiment described in the patent specification. *Smith*, 294 U.S. at 11 ("the claims of the patent, not its specifications, measure the invention."); *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) ("[the statutorily required] distinct and formal claim is, therefore, of primary importance, in the effort to ascertain precisely what it is that is patented to the appellant in this case.").

The Federal Circuit decision here disregards this binding law and utterly lacks any analysis that is based on the text of the claims. The court did not "resort . . . in the first instance to the words of the claim," *Graver Tank & Mfg. Co.*, 339 U.S. at 607; to the contrary, the court ignored and never discussed over half of the claims that are being asserted. A claim never discussed is a "patented invention" ignored. *See Graver Tank & Mfg. Co.*, 336 U.S. at 277 ("It would accomplish little to require that claims be separately written if they are not to be separately read."); *Altoona Publix Theatres*, 294 U.S. at 487 ("The Court of Appeals, in upholding the patent, made no examination of its separate claims. . . . And each claim must stand or fall, as itself sufficiently defining invention, independently of the others."). That the court ignored so many of the asserted claims while at the same time purporting to construe all 92 asserted claims for the first time on appeal without the benefit of any construction by the trial court reveals clearly the flawed methodology that the majority employed. App. 26a-27a.

The Federal Circuit made it quite clear that it defined "the invention" by the patents' common specification, not their varied claims, disregarding 35 U.S.C. § 112 and this Court's admonition that "the claims of the patent, not its specifications, measure the invention." *Smith*, 294 U.S. at 11. If it is "unjust to the public" and an "evasion of the law" to construe a claim "in a manner different from the plain import of its terms," *White v. Dunbar*, 119 U.S. 47, 52 (1886), then surely it is equally "unjust" and an "evasion of the law" to ignore the claim terms altogether and define a patented invention by its specification. Yet that is exactly what the Federal Circuit did here.

The Federal Circuit's use of "prosecution disclaimer" to prop up its conclusion further highlights its disregard for the claim text and the conflict with this Court's precedent, which ties the relevance of a prosecution history to the language of the claims. *Smith* held that a prosecution history (also called the file wrapper) can be relevant to prevent a patentee from "broaden[ing] his claim by dropping from it an element which he was compelled to add in order to secure his patent." 294 U.S. at 14-15. Thus, in *Smith v. Snow* the Court looked first to the language of the claims and then to the prosecution history *of the claim in suit* to determine if the patentee had restricted the claims to obtain allowance (and found that he had not). *Id.* at 15-16. Use of the prosecution history to limit claims without regard to the claim language conflicts with *Smith* and finds no support in this Court's precedents.

Searching for the essence or heart of "the invention" is a form of claim construction that, as the dissent observed, this Court soundly rejected in *Aro Mfg. Co.*, 365 U.S. at 345 ("there is no legally

recognizable or protected 'essential' element, 'gist' or 'heart' of the invention in a combination patent"). The invention is defined by the claims, and it is only by looking to the words in the claim, not some purported "essence" or "nature" of the invention, that courts can adhere to Congress's goal of giving interested persons notice of what is and is not patented.

The approach adopted by the majority below is akin to a method of statutory interpretation this Court abandoned more than two decades ago. In the middle part of the last century, it was common for courts to interpret statutes primarily by reference to legislative history and the overall policy of the law. *See* William N. Eskridge, Jr., *The New Textualism*, 37 UCLA Law Rev. 621, 626-628 & nn.16, 25 (1990) (collecting examples from this Court's case law from the 1920s through the 1980s); *see also, e.g., United Steelworkers v. Weber*, 443 U.S. 193, 201 (1979) (refusing to adopt "a literal interpretation" of Title VII's text and turning instead to its legislative history and "the historical context from which the Act arose"). Beginning in the 1980s this Court adopted a more rigorous approach to statutory interpretation that "always" focuses in the first instance on the language of the law. *See, e.g., Knight v. C.I.R.*, 128 S.Ct. 782, 787 (2008); *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002); *United States v. Gonzales*, 520 U.S. 1, 4 (1997). If the language is unambiguous, the inquiry ends there as well. *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 98 (2004). If there is a lack of clarity in the language, then the Court turns to additional sources—the structure and history of the statute, rules of construction and on occasion legislative history. *See, e.g., Dolan v. U.S. Postal Serv.*, 546 U.S. 481, 486 (2006); *Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 60-64 (2004); *Florida*

Power & Light Co. v. Lorion, 470 U.S. 729, 737 (1985). But even in this process, the Court does not ignore the text of the statute.

The Court should adopt the same approach to patent claim construction that it has applied in the construction of statutes. The Federal Circuit's willingness to deviate from the language of the patent claim and to find its meaning from atextual sources does the same kind of damage to the Congressional policies underlying the Patent Act that judicial departures from the language in a statute do to the separation of powers. The appropriate solution in both instances is the same. Fundamentally, the process of claim interpretation must remain just that: it must be a matter of supplying the correct meaning to the words of the text that is under scrutiny, and not a vehicle for rewriting the text according to the judicial decision maker's sense of what it should have said.

The Federal Circuit's erroneous approach of defining patented rights by abandoning the text of the claims is binding law that is applicable in every patent case. The court's decision here impacts every single patent. Its impact is not limited to infringement and validity issues in patent litigation. It impacts how intellectual property rights are valued, and thus materially affects the business interests of many corporations, both large and small. The uncertainty it has created over what patents protect adversely affects decisions made by the Patent Office, patentees, competitors, investors and, of course, lawyers who must render advice. Only this court can clarify the proper rule of construction for patents and restore the primacy of claim language that is critical to the public notice function of the patent system.

II. THE CONFLICT IS ONGOING AS FEDERAL CIRCUIT PANELS ARE SPLIT ON THIS ISSUE AND THE FEDERAL CIRCUIT HAS PROVED UNABLE OR UNWILLING TO RESOLVE THIS FUNDAMENTAL AND RECURRING PROBLEM.

The majority's decision reflects a methodological conflict within the Federal Circuit that is recurring and will persist until this Court finally resolves it. This case is only the most recent example, but one that renders the conflict readily apparent.

As the dissent here pointed out, the Federal Circuit would have come to a different result had it decided this case under its law as set forth in *Ventana Medical Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173 (Fed. Cir. 2006). App. 36a. In *Ventana*, the majority started with the words at issue in the claim and the rule that claim terms are given their "ordinary and customary meaning" unless something in the specification or prosecution history reflected the inventor's intent that one of ordinary skill should interpret the claim term differently. *Id.* at 1180. Since it anchored its analysis to the words in the claim, the *Ventana* court found the prosecution history of an ancestor patent irrelevant because the claim terms at issue in the prosecution were different than the claims term being interpreted. *Id.* at 1182. It was the *dissent* in *Ventana* that argued that the "essence of the invention" could be gleaned from the specification and prosecution history, and that the claims should be limited to that invention. *Id.* at 1186 ("Direct dispensing is the essence of the invention, and the specification supports that conclusion.") (Lourie, J., dissenting). The dissent in *Ventana*

became the Federal Circuit's contrary but still binding precedent in this case.

Congress established the Federal Circuit with exclusive jurisdiction over patent cases hoping to bring greater uniformity to the patent law. *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, 527 U.S. 627, 651 (1999); *United States v. Hohri*, 482 U.S. 64, 71 (1987). Yet at least since *Markman*, the Federal Circuit has employed inconsistent claim construction methodologies and the "law" as applied has varied by panel, with a welter of published cases on both sides of the issue. Some Federal Circuit cases start with the text of the claims, and then presume that the text will be given its ordinary meaning, absent clear indications that persons skilled in the art would understand some other meaning. *See e.g.*, *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) ("a claim construction analysis must begin and remain centered on the claim language itself"); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("[T]he resulting claim interpretation must . . . accord with the words chosen by the patentee . . . ."); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 865-66 (Fed. Cir. 1997) (concluding that intrinsic evidence does not require modification of the ordinary meaning of "reciprocating"); *York Prods., Inc. v. Cent. Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1572 (Fed. Cir. 1996) ("Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning."). Other Federal Circuit cases, by contrast, take a decidedly atextual approach. They determine coverage by looking mainly to the specification and prosecution history, not the claims, to divine "the invention" from

context and limit the patent rights to that "invention." *See e.g., Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375-82 (Fed. Cir. 2003) (Schall, J., dissenting) (dissent explaining how majority departed from precedent and "arrived at its conclusion that the asserted claims require play by relying on [statements in the specification]" and the prosecution history of a parent patent, not the claims); *see also Cultor Corp. v. A.E. Staley Mfg.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Whether a claim must, in any particular case, be limited to the specific embodiment presented in the specification, depends in each case on the specificity of the description of the invention . . . ."); *Toro Co. v. White Consol. Indus.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999) ("The specification does not describe an invention broader than [the] description of the cover and the restriction ring 'automatically' inserted and removed together."). These two groups of cases are inconsistent with each other. In fact, one Federal Circuit panel characterized the court's claim construction rules as "ambivalent" and observed that their "careless application . . . can be a recipe for error." *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003).

Scholarly studies have recognized and documented the deep and irreconcilable conflict in the Federal Circuit's claim construction methodologies. A recent study identified two conflicting methodologies employed by the Federal Circuit: one favoring the ordinary meaning of the text; the second "distinctly more free-form" and based more heavily on nontextual sources. R. Polk Wagner & Lee Patherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. Pa. L. Rev. 1105, 1111-12 (2004). Professor Wagner con-

cluded that a "sharp division" exists within the court as to the proper approach, that the Federal Circuit's cases were becoming "increasingly polarized," and that the outcome of cases are panel dependent and judge dependent. *Id.* at 1111. Another study published by now Judge Kimberly Moore in 2005 concluded that the Federal Circuit's reversal rate of 35% on claim construction issues was getting "worse over time, not better" and that "criticism over the lack of guidance and unpredictability caused by the current claim construction process is warranted." Kimberly Moore, *Markman Eight Years Later: Is Claim Construction More Predictable*?, 9 Lewis & Clark L. Rev. 231, 233, 237 (2005).

In 2005 the Federal Circuit granted *en banc* review to address claim construction in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). The decision, although met with great fanfare and a plethora of amicus briefs, produced little more than a restatement of the Federal Circuit's earlier opinions. *Id.* at 1312 ("what we said in those cases bears restating"); *see also id.* at 1330 ("[A]fter proposing no fewer than seven questions, receiving more than thirty *amici curiae* briefs, and whipping the bar into a frenzy of expectation, we say nothing new, but merely restate what has become the practice over the last ten years – that we will decide cases according to whatever mode or method results in the outcome we desire, or at least allows us a seemingly plausible way out of the case.") (Mayer, J., dissenting). Thus, while the *Phillips*' majority stated that "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude,'" *id* at 1312, it also equivocated and left unresolved whether a claim

construction must start with the words of the claim and remain anchored to the disputed claim terms.

Phillips used language favoring an atextual approach to claim construction rather than an approach focused on the text of the claims: "the court *starts* the decision-making process by reviewing the same resources as would [a person of ordinary skill in the field of the invention], *viz.*, the patent specification and the prosecution history." *Id.* at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)) (emphasis added). The court also stated that "[t]he sequence of steps used by the judge in consulting various sources [such as the specification, prosecution history, or dictionaries] is not important." *Id.* at 1324. Indeed, Judge Lourie, joined by Judge Newman, concurred in the court's explication of its claim construction methodology, expressly interpreting *Phillips'* holding to be that claims "are limited to what is contained in the overall disclosure of the specification." *Id.* at 1328-29 (Lourie, J., concurring in part and dissenting in part). This is but another way of saying that the specification defines the patented inventions. That interpretation has resulted in the instant decision, where the patent claims are entirely disregarded.

Thus, the methodological conflict continues post-*Phillips*, and whether the Federal Circuit gives primacy to the claim language continues to be panel dependent and unpredictable. As one author who examined Federal Circuit law post-*Phillips* concluded: "The name of the game is no longer just the claim. It's the whole patent." Gerson Panitch, *Is the Name of the Game Still the Claim? The Post-Phillips Revolution in Patent Law*, Intellectual Property Today (June 2007). Even though the Federal Cir-

cuit's decision here conflicts both with *Ventana* and this Court's precedents, the Federal Circuit denied rehearing *en banc* and let the conflict stand. The Federal Circuit's decision here sanctions continued use of sources other than the claim language to define the "patented invention." The Federal Circuit remains polarized, and it is plain that a workable, predictable methodology for determining the scope of a patent will require renewed guidance from this Court.

III. THE COURT SHOULD FINALLY RESOLVE THIS RECURRING CONFLICT THAT UNDERMINES CONGRESS'S POLICY DECISION TO PROTECT INTELLECTUAL PROPERTY RIGHTS THROUGH PATENT LAW.

This Court has often observed that the patent laws reflect a policy decision that intellectual property protection through patent rights can have a strong positive effect on technological change and therefore on economic growth. *Bonito Boats Inc.*, 489 U.S. at 150-51; *Festo Corp.*, 535 U.S. at 730-31. The statutory requirement that the claims define the patentee's rights distinctly and with particularity is important both to providing the patentee with an appropriate incentive for invention and disclosure and for providing notice to the public. "[C]larity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not." *Festo Corp.*, 535 U.S. at 730-31. For example, if the public cannot determine what the patent protects by looking at the claims, third parties may avoid activities that are not claimed as the invention (and thus are free for the

public to use) for fear of being sued nonetheless for infringement. In addition, an inventor who cannot be reasonably certain that his claims define his patent protection may choose to avoid the patent system altogether and maintain his invention as a trade secret.

Clear and predictable boundaries can be delineated only by faithful adherence to the text of the claims. *See Keystone Bridge Co. v. Phoenix Iron Co.*, 95 U.S. 274, 278 (1877) (statutory requirement that a patent include one or more claims "was inserted in the law for the purpose of relieving the courts from the duty of ascertaining the exact invention of the patentee by inference and conjecture"). There is no clarity or predictability when the scope of a patented invention remains highly uncertain until appeal and even then is panel and judge dependent. The Federal Circuit's failure to heed the mandate of the statute and this Court's precedent, combined with its continued internal dispute over whether to adhere to the text of the claims, affects every patent, goes to the very heart of infringement and patentability—defining what is the patented invention—and subverts the very policies the patent laws are intended to promote.

Even the Federal Circuit recognizes the problem of a jurisprudence where it finds that district courts get claim construction wrong as a matter of law over 35% of the time. *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1266 (Fed. Cir. 2005) ("For various reasons this court already has a high reversal rate on claim construction issues, which tends to encourage appeals and, perhaps, discourage trial courts from heavily investing in claim constructions below."). Similarly, district courts have openly expressed bewilderment over how to apply the applicable law

and seemingly approach the undertaking with a sense of fatalism.[4] The Federal Circuit has chosen to do nothing, however, to resolve this ongoing and pervasive problem in its law. Because the Federal Circuit is either unable or unwilling to resolve the conflict and is unlikely to attempt to do so again in the foreseeable future, the time has come for this Court to make clear that it meant what it said in its prior decisions—claim construction begins and never deviates from the text of the claims.

This Court has not addressed claim construction rules since long before the creation of the Federal Circuit. The issue presented requires no subtle or detailed analysis of a specification or file history to determine the "correct" claim construction for any of the 92 asserted claims in this case. Rather, the question presented is whether a court can conduct, to quote the dissent, "a form of claim construction," without ever identifying what claim terms are in need of construction or why. Absent review by this Court, patent rights will be undermined and the public notice function of the patent claims will

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[4] *Merck & Co., Inc. v. Teva Pharma. USA, Inc.*, 395 F.3d 1364, 1381 (Fed. Cir. 2005) (noting that the Federal Circuit "often hears criticism from district court judges that its reversal rate on claim construction far exceeds that of other circuit courts); *Ultratech, Inc. v. Tamarak Scientific Co.*, 2005 WL 2562623 at *7 (N.D. Cal. Oct. 11, 2005) ("Nor can the Court say that *Ultratech's* claim construction position is so frivolous as to warrant sanctions; to be candid, this Court is reluctant to hold that any claim construction is frivolous, given the well-known reversal rate in the Federal Circuit."), *Cargill, Inc. v. Sears Petroleum & Transport Corp.*, 2004 WL 3507329 at *12 (N.D.N.Y. Aug. 27, 2004) (staying permanent injunction pending appeal and noting that "I am also cognizant of the Federal Circuit's unusually high rate of reversal, particularly when engaged in de novo review of claim construction").

continue to be frustrated because patent holders and the public alike will be left uncertain as what is the patented invention.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A

United States Court of Appeals
for the Federal Circuit

2006-1240, -1274

ORMCO CORPORATION
Plaintiff/Counterdefendant-Appellant,

and

ALLESEE ORTHODONTIC APPLIANCES, INC.,
Counterdefendant,

v.

ALIGN TECHNOLOGY, INC.,
Defendant/Counterclaimant-Cross Appellant.

David L. DeBruin, Michael, Best & Friedrich, LLP, of Milwaukee, Wisconsin, argued for plaintiff/counter-defendant-appellant. With him on the brief were *Charles J. Crueger* and *Richard H. Marschall*.

Anne M. Rogaski, Townsend and Townsend and Crew LLP, of Palo Alto, California, argued for defendant/counterclaimant-cross appellant. With her on the brief were *Daniel J. Furniss*, *Gary H. Ritchey*, and *Nancy L. Tompkins*.

Appealed from: United States District Court for the Central District of California

Judge Christina A. Snyder

United States Court of Appeals
for the Federal Circuit

2006-1240, -1274

ORMCO CORPORATION
Plaintiff/Counterdefendant-Appellant,

and

ALLESEE ORTHODONTIC APPLIANCES, INC.,
Counterdefendant,

v.

ALIGN TECHNOLOGY, INC.,
Defendant/Counterclaimant-Cross Appellant.

DECIDED: August 24, 2007

Before LOURIE and DYK, *Circuit Judges*, and O'MALLEY, *District Judge*.*

Opinion for the court filed by *Circuit Judge* LOURIE. Opinion concurring in part and dissenting in part filed by *District Judge* O'MALLEY.

LOURIE, *Circuit Judge*.

Ormco Corporation ("Ormco") appeals from the decision of the United States District Court for the Central District of California granting summary judg-

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* Honorable Kathleen M. O'Malley, District Judge, United States District Court for the Northern District of Ohio, sitting by designation.

ment in favor of Align Technology, Inc. ("Align") that the asserted claims of Ormco's U.S. Patents 6,616,444 ("the '444 patent"), 6,244,861 ("the '861 patent"), 5,683,243 ("the '243 patent"), and 5,447,432 ("the '432 patent) (collectively, the "Ormco patents") were not infringed and are invalid. Align cross-appeals from the decision of the trial court granting summary judgment of invalidity of certain claims of Align's U.S. Patent 6,398,548 ("the '548 patent") in favor of Ormco and Ormco's subsidiary, Allesee Orthodontic Appliances, Inc. ("AOA"). Because the court correctly granted summary judgment as to some but not all of the claims of the Ormco patents, we affirm in part and reverse in part the judgment as to the Ormco patents. Because the court correctly granted summary judgment of invalidity of the specified claims of the '548 patent, we affirm that judgment.

BACKGROUND

Ormco filed suit on January 6, 2003, alleging that Align's Invisalign® process infringed the '861, '243, and '432 patents. Ormco later amended its complaint to allege infringement of the '444 patent as well. Ormco alleges infringement of claims 1-5 and 8-79 of the '444 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; claims 1 and 2 of the '243 patent; and claims 1, 9, and 10 of the '432 patent. The Ormco patents relate to the computer-aided design and manufacture of custom orthodontic appliances. They share a common specification, which is also shared with additional patents not asserted in this suit, including U.S. Patent 5,431,562 ("the '562 patent"). The '562 patent is a parent of the '243 patent, the '861 patent, and the '444 patent. The application leading to the '562 patent was filed on the same day as the application leading to the '432 patent.

Align counterclaimed for declaratory judgment of noninfringement and invalidity and also alleged infringement by Ormco and AOA of U.S. Patent 6,554,611 ("the '611 patent") and the '548 patent. The '611 and '548 patents relate to the use of a series of individual orthodontic appliances to incrementally reposition teeth.

In a May 13, 2004, Order, the trial court granted Align's motion for summary judgment of noninfringement. *Ormco Corp. v. Align Tech., Inc.*, No. 03-cv-00016, slip op. (C.D. Cal. May 13, 2004). In that Order, the court found that statements in the shared specification of the Ormco patents, the prosecution history of the '562 patent, the prosecution history of the abandoned 07/775,589 application (of which the '432 patent is a continuation-in-part), and the prosecution history of the '432 patent limited the claims of the Ormco patents to a process in which final treatment positions for teeth are automatically determined. The court then determined that there were no genuine issues of material fact precluding summary judgment. The court accordingly granted summary judgment of noninfringement in favor of Align because Align's system relies on "skilled operators" rather than computers to determine the finish positions of the teeth.

The court also granted Align's motion for summary judgment of nonenablement of Ormco's patents on August 20, 2004. *Ormco Corp. v. Align Tech., Inc.*, No. 03-cv-00016, slip. op. (C.D. Cal. Aug. 20, 2004). In determining whether Align had presented clear and convincing evidence of nonenablement, the court relied on its prior ruling that "the scope of Ormco's claims [was] limited to 'automatic computer determination of the finish positions of teeth.'"

In reviewing the evidence, the court first noted testimony from the inventors indicating that Ormco software had never been used to automatically determine tooth positions without any human intervention. The court found that additional testimony from one inventor that the unmodified output of Ormco's first software design, the Elan, had been used to generate appliances for actual patients was not credible because of the lack of corroboration from documents or other sources. The court also found that the statements of Ormco's expert, John Grubb, that Elan had been used to treat patients without operator intervention were also not credible because his expert report lacked sufficient foundation to support such an opinion. The court further found other statements from the inventors unpersuasive because they were equivocal and indicated at best that the Elan software might be used to treat patients without human adjustment of tooth positions, but not that the software had actually been used in such a way. The court also found testimony that Ormco's new software, the Insignia, could be used to automatically generate orthodontic appliances similarly unpersuasive in light of the fact that the manual override had been used in all forty of the test cases using that software.

Finally, the court granted summary judgment of invalidity of claims 1-3 and 11-13 of Align's '548 patent in favor of Ormco and AOA on February 25, 2005. *Ormco Corp. v. Align Tech., Inc.*, No. 03-cv-00016, slip. op. (C.D. Cal. Feb. 25, 2005). The court first construed the claim terms "system" and "geometry," using a dictionary to give them their ordinary meaning. The court then determined that Dr. Rains' use of the STARS system for orthodontic treatment anticipated all of the limitations of claims 1-3 and 11-13 of the '548 patent. The court rejected Align's

arguments that a "system" required that the orthodontic appliances be produced at the same time and that "mark[ing]" the appliances required that the marks indicate order of use to the patient, rather than the orthodontist.

Ormco timely appealed, and Align timely cross-appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review *de novo* a grant of summary judgment by a district court. *Optivus Tech., Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 984 (Fed. Cir. 2006). Summary judgment is appropriate if "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "When ruling on a motion for summary judgment, all of the nonmovant's evidence is to be credited, and all justifiable inferences are to be drawn in the nonmovant's favor." *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 1379 (Fed. Cir. 2000).

A. Noninfringement

"We review a district court's grant of summary judgment of non-infringement without deference." *02 Micro Intl, Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1359 (Fed. Cir. 2006). Our *de novo* review of summary judgment of noninfringement requires two steps—claim construction, which we review without deference, and infringement, which we review to determine whether there was no genuine issue of material fact. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

On appeal, Ormco argues that the district court erred when it interpreted the claims to require auto-

matic determination of finish tooth positions, contrary to their plain language, and when it failed to tie that interpretation to specific language in each claim. Ormco further argues that the statements referenced by the court to support its application of the automatic determination limitation do not meet the standard for an intentional disavowal of claim scope and that statements from the prosecution history of the '562 patent are limiting only as to the particular claim language with respect to which they were made (*e.g.*, "ideal dental archform").

In response, Align argues that a patentee can make a disavowal of scope as to the general nature of an invention that in turn limits all claims even though specific claim language is not being interpreted. Align argues that the statements in the Ormco patents' specification and the prosecution history of the '562 patent constitute such a disclaimer. In the alternative, Align argues that all of the asserted claims except claims 37-40, 45, and 69 of the '444 patent contain express language that requires a construction that includes the automatic determination limitation.

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation and internal quotations omitted); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."). However, "claims 'must be read in view of the specification, of which they are a part,'" *Philips*, 415 F.3d at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)), and "[t]he

construction that stays true to the claim language and *most naturally aligns with the patent's description of the invention* will be, in the end, the correct construction," *id.* at 1316 (quoting *Renishaw PLC v. Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)) (emphasis added).

Consistent with that precedent, we conclude that the district court correctly determined, as to most, but not all, of the asserted claims of the Ormco patents, that requiring automatic determination of finish tooth positions is a proper construction of the asserted claims. Interpreting most of the claims to require automatic determination of finish tooth positions "most naturally aligns with the patent's description of the invention." From the beginning of the common specification of the Ormco patents, it is clear that the inventors' primary basis for distinguishing their invention was its high level of automation in the design of custom orthodontic appliances as compared to the prior art. In the Background of the Invention, the inventors stated, "In reality, the treatment of patients is in many cases more of an art than a science, with results ranging from poor to excellent, and generally variable." '444 patent col.3 ll.7-10. The inventors specifically stated that the prior art had encountered difficulties in "the task of developing an *automated* system that includes reliable and efficient *decision making algorithms* and techniques *for automatically determining an ideal finish position of the teeth*." *Id.* at col.3 ll.17-22 (emphases added).

The specification then indicates a clear emphasis in the patent on removing the referenced variability in the orthodontic treatment process by relying on a predetermined set of calculations rather than human judgment to determine final tooth positions. "A pri-

mary objective of the present invention is to provide a practical, *reliable* and efficient custom appliance *automated design* and manufacturing system and methods of *automatically designing* custom orthodontic appliances and treating patients therewith." '444 patent col.3 ll.41-45 (emphases added). "In accordance with the preferred embodiment of the present invention, there is provided *a computerized system* and method with which *finish positions of the teeth* of a patient are *derived* from digitized information of anatomical shapes of the patient's mouth . . . ." '444 patent col.4 ll.16-20 (emphases added). "*The computer* 30b at the appliance facility 13 *calculates*, based on the digitized information 26, *the final position of the patient's teeth* . . . ." '444 patent col.14 ll.6-8 (emphases added).

Nowhere does the specification suggest or even allow for human adjustment of the computer-calculated tooth finish positions. Statements in the specification cited by Ormco to support human participation in the process are limited to input from the orthodontist and/or computer operator at the *start* of the process (*i.e.*, when particular "landmarks," data points related to teeth and jaw anatomy and geometry, are selected for input into the automatic calculation process) and not related to determination of tooth finish positions. *See, e.g.*, '444 patent col. 10 l.63—col. ll l.2, col.13 ll.51-57. The first of those passages again emphasizes that the invention "applies automated decision making processes in the appliance design." *Id.* at col.10 ll.66-67.

The specification goes on to state, "In the *computer analysis procedure* (95), the digitized information input by the input procedure (94) is analyzed to calculate *the finish position of the teeth*, so that the cus-

tom appliance (25) can be designed in computerized design procedure (96) and manufactured in computer controlled manufacturing procedure (97)." *Id.* at col.24 ll.25-30 (emphases added). Further, the detailed recitation of the formulas and algorithms for automatic calculation of final tooth positions that follows, *see id.* at col.39 l.41—col. 53, l. 52, concludes with the statement, "At this point, the final positions of the maxillary teeth have been calculated, and thus, the finish positions of all of the teeth." *Id.* at col.53 ll.50-52. There is no discussion of operator or orthodontist review or adjustment of those finish positions or of the bases on which such review and adjustment might be made. Instead, the specification turns to a description of the "Appliance Design Procedure," which utilizes the finish tooth positions that have been automatically determined. The specification thus provides clear indication that the invention is in the automatic determination of tooth position.

While all those statements by the inventors in the specification of the Ormco patents, standing alone, may not be conclusive in showing that the claims require completely automatic determination of final tooth positions, those in the prosecution history make it even clearer. "[T]he prosecution history can often inform *the meaning of the claim language* by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317 (emphasis added). Thus, we turn to the prosecution history of the Ormco patents, and other patents from the same family, to determine if there are statements there that should further inform our construction of the claims. As the district court correctly observed, we have held that "prosecution dis-

claimer may arise from disavowals made during the prosecution of ancestor patent applications." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1333 (Fed. Cir. 2003). When the application of prosecution disclaimer involves statements from prosecution of a familial patent relating to the same subject matter as the claim language at issue in the patent being construed, those statements in the familial application are relevant in construing the claims at issue. *See, e.g., Wang Lab., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999); *Jonsson v. Stanley Works*, 903 F.2d 812, 818 (Fed. Cir. 1990). In this case, the specifications of the prior '562 patent, which is the parent of three of the patents in issue, and all the presently litigated patents, have the same content. Thus, the prosecution history of the claims of application number 07/973,973, which led to the '562 patent, are relevant in construing the claims of the '432, the '243, the '861, and the '444 patents.

The claims of the parent 07/973,973 application were rejected by the United States Patent and Trademark Office ("PTO") under 35 U.S.C. § 103 in an Office Action on September 13, 1993, based in part on U.S. Patent 5,011,405 to Lemchen. In a Response on March 16, 1994, the inventors made a number of statements characterizing the Lemchen patent and seeking to distinguish their invention. The first part of the Response describing Lemchen, noted by the district court, states:

> Using such a CAD [computer-aided design] program in a conventional manner, as Lemchen describes, *an operator would manipulate* the tooth images to provide the desired occlusion. This would presumably involve *some decision making* by the operator. As the operator manipulates the

> images, the computer, under the control of the conventional CAD program, would perform the calculations that would generate data of the tooth movements made by the operator and thus of the finish positions of the teeth.

(emphases added). This passage illustrates the inventors' characterization of the Lemchen prior art, *viz.*, that it involves use of an operator. The inventors then distinguish between their automated design process and processes that are merely computer assisted and involve human input in a further characterization of the Lemchen patent:

> The Lemchen patent relies, to produce the calculations, on the conventional calculation techniques employed in generalized CAD software. This in turn relies on a user interactive interface by which an *operator contributes human decision making* powers to manipulate images until the operator is satisfied that finish tooth position criteria have been met. . . . However, with conventional CAD programs, the reliance on human decision making is heavy, and *rigorous fully automated arrival at tooth finish positions is lacking.*

(emphases added). The inventors thus distinguished Lemchen by emphasizing its reliance on an operator for the decision-making process.

Further statements by the inventors in arguing for allowance of their claims in their Response continued to characterize their method by which final tooth positions may be determined. They stated, "The present invention of applicants is directed toward the most complete and *fully automated* method for orthodontic appliance design and manufacture made." (emphasis

added). None of the prior statements in the Response were limited to particular claims. Again, in a section entitled "Deriving Finish Positions from Derived Ideal Dental Archform," the inventors argued, "The judgment, or decision making, on the acceptability of tooth positions must be imposed externally of Lemchen's system. This leads to human error and inconsistencies from patient to patient. Lemchen does not disclose this being done automatically thereby avoiding such errors and inconsistencies." In that same section, the inventors conclude, "Therefore, Lemchen, while primarily concerned with bracket placement, uses a user interactive computer system to calculate tooth finish positions, [but] applicants have provided a computerized system with the intelligence to decide *for itself* the best finish positions of the teeth." (emphasis added). That statement was directed to amended claims 1-30, 35-38, and 65-72, but was not associated with particular language from those claims. Furthermore, the method of amended claim 1 included the step of "deriving with the computer tooth finish positions," demonstrating that the same subject matter of automatic determination of finish tooth positions was included in those claims. In an effort to further bolster their arguments to the examiner, the applicants also submitted a Declaration from an orthodontist, Michael W. Scott. Dr. Scott's declaration states, "In applicants' overall method, it is a computer, not an orthodontist or an orthodontically skilled computer operator that makes the decision on the finish positions in which the teeth are to be placed."

With these and other similar statements from the prosecution history of the '562 patent in mind, we address the claims of the Ormco patents involved in this lawsuit. Ormco has asserted infringement of

claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 10-17, 23-29, 30-36, 46-68, and 70-79 of the '444 patent.

All of the above claims require determining the finish positions of the teeth. *E.g.*, '432 patent, claim 1 ("producing desired tooth position signals containing digitized data of desired positions of a plurality of the patient's teeth"); '243 patent, claim 1 ("a computer programmed . . . to calculate finish positions of the teeth of the patient"); '861 patent, claim 1 ("determining treatment positions of the teeth"); '444 patent, claim 10 ("a computer programmed to apply at least some automated tooth position criteria to produce a digital model of the teeth of the sca ned shapes in desired positions"). Although their claim language does not expressly recite automatic control of the finish tooth positioning, that is what they mean, and that is all that the specification describes; the specification does not support operator positioning. Moreover, the prosecution of the '562 patent, with the same specification, makes clear that the inventors understood their invention to encompass only automatic positioning because they so argued in order to distinguish their claims over Lemchen. We are mindful of the precaution that we must not incorporate into the claims limitations only found in the specification. We are not doing so here, nor did the district court. We are interpreting the claims in light of the specification. The situation here involves specifications that in all respects tell us what the claims mean, buttressed by statements made during prosecution in order to overcome a rejection over prior art. Accordingly, to attribute to the claims a meaning broader than any indicated in the patents and their prosecution history would be to ignore the totality of

the facts of the case and exalt slogans over real meaning. We thus agree with the district court that in light of the specification of the Ormco patents and statements from the prosecution history of the parent '562 patent, the claims specified above require automatic computer determination of the finish positions of the teeth without human adjustment of the final results.

Ormco has also asserted infringement of claims 1-5, 8, 9, and 18-22 of the '444 patent. Claims 2-5, 8, and 9 depend from independent claim 1. The method of claim 1 does include the limitation "through an operator interacting with a computer located remote from the orthodontic practitioner, altering the graphic representation to arrange a plurality of the teeth in relation to each other in accordance with the prescription, to produce a digital model of a desired arrangement of the teeth of the patient." Ormco argues that the specific recitation of an operator in this clause differentiates this claim from other claims in which the operator is not mentioned and supports the scope of the claim to allow for the operator to select the finish tooth positions or at least aid in the process. We do not agree. The role of an operator in this claim and its dependent claims is only to help generate and enter the tooth data into the computer that is needed for the automatic process to operate. The operator does not determine the finish positions of the teeth; that is still done automatically. Thus the district court did not improperly construe claims 1-5, 8, and 9 of the '444 patent to require automatic determination of tooth positions.

The method of claim 18 includes the limitation of "a computer . . . programmed to select geometric parameters on the patient's teeth from the digitized

data by operator-interaction and to produce a digital model of the teeth in desired positions." Claims 19-22 of the '444 patent depend from independent claim 18. As with claim 1, the fact that a role for the operator is required by the claim language at the beginning of the process does not support Ormco's argument that determination of finish tooth positions in claim 18 is not done automatically. Thus, in light of the specification of the Ormco patents and statements from the prosecution history of the '562 patent as a whole, "altering the graphic representation to arrange a plurality of the teeth in relation to each other . . . to produce a digital model of a desired arrangement of the teeth of the patient" and "produc[ing] a digital model of the teeth in desired positions" each require automatic computer determination of the finish positions of the teeth without human adjustment of the final results.

We reach a different conclusion with respect to claims 37-40, 45, and 69. The district court treated those claims in the same manner as all the others. Align argues that the methods of claims 37-40, 45, and 69 similarly relate to automatic design or automatic calculation of finish tooth positions. We do not agree. Those claims relate to the preliminary gathering and organization of tooth data as an aid to further unspecified orthodontic treatment or for use in creation of a digital model, not to the specific automatic determination of finish tooth positions. Such preliminary gathering and organization do not, by themselves, determine finish tooth positions. We therefore conclude that claims 37-40, 45, and 69 do not require automatic computer determination of finish positions of teeth, and that the district court thus erred in so concluding. However, each of the dependent claims 41-44 requires "manipulating the

separate digital representations of the generated data in a computer to rearrange the shapes of the individual teeth" into "desired relative positions." Such rearrangement requires determination of the finish positions of the teeth and therefore as with the other claims in suit discussed previously, automatic determination of those finish positions is implicit in those claims. Thus, in light of the specification of the Ormco patents and statements from the prosecution history of the '562 patent as a whole, "manipulating . . . the individual teeth" into "desired relative positions" requires automatic computer determination of the finish positions of the teeth without human adjustment of the final results.

In summary, we conclude that all of the asserted claims of the Ormco patents, except claims 37-40, 45, and 69 of the '444 patent, require automatic computer determination of the finish positions of the teeth without human adjustment of the final results. Since Ormco does not challenge the district court's finding that Align relies on skilled operators rather than a fully automated computerized process to determine finish positions of the teeth, we affirm the district court's grant of summary judgment of noninfringement as to claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 1-5, 8-36, 41-44, 46-68, and 70-79 of the '444 patent. However, because claims 37-40, 45, and 69 of the '444 patent do not require automatic computer determination of teeth finish positions, we reverse the district court's grant of summary judgment of noninfringement as to those claims and remand for further proceedings consistent with this opinion.

We accept that Ormco's argument, and that of the dissent, that the district court failed to conduct a claim construction in this case focusing on specific claim language, is not lacking in force. However, we review decisions, not opinions, *see Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983), and when we are able to fully comprehend the specification, prosecution history, and claims and can determine that, to the extent we have indicated, the district court arrived at the correct conclusion, we need not exalt form over substance and vacate what is essentially a correct decision.

B. Nonenablement

Enablement is a question of law that we review *de novo*. *Liquid Dynamics, Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1224 (Fed. Cir. 2006). As this was a summary judgment determination, all facts must be construed in the light most favorable to the nonmoving party. The party alleging invalidity for lack of enablement bears the burden of proving by clear and convincing evidence that the specification of a challenged patent fails to teach one of ordinary skill in the art how to make the invention. *See Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1186 (Fed. Cir. 2002); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1378 (Fed. Cir. 1999).

As an initial matter, the district court's grant of summary judgment of nonenablement hinged upon its construction of the claims of the Ormco patents. Because the court erred in construing claims 37-40, 45, and 69 of the '444 patent, we reverse the grant of summary judgment of nonenablement as to those claims and remand for further proceedings consistent with this opinion.

As for the other claims, Ormco argues that the determination of enablement should focus only on the specification of its patents rather than on its development work on its commercial Elan and Insignia software. In the alternative, Ormco argues that its evidence demonstrated that the Elan and Insignia products were capable of automatically determining final tooth positions. Align responds that an inventor's inability to actually practice his invention is proof of lack of enablement, that mere uncorroborated inventor testimony on enablement is insufficient to create triable issues of fact, and that the method taught in the specification of the Ormco patents cannot determine useful tooth finish positions because it fails to account for the initial tooth positions and thus fails to address problems such as tooth collisions or excessive application of force.

We agree with the district court's summary judgment on enablement. The district court reviewed deposition testimony of the inventors stating that the Elan and Insignia software incorporated the automatic determination aspect of the invention, but did not accept that assertion as sufficient to create triable issues of fact given other more specific admissions by the inventors. Ormco has implicitly conceded that the Elan and Insignia software represented attempts to follow the patents' specifications by arguing that those products demonstrated enablement of the Ormco patents.

But during his May 12, 2004, deposition, Dr. Andreiko, one of the inventors of the Ormco patents, testified that Ormco had never attempted to create a computerized system that automatically determined tooth positions without human decision making. He also testified that the manual override had been used

on all of the approximately forty cases treated using the Insignia product and that, while it was a goal to have the software generate final tooth positions that would not require use of the override, variations in human anatomy had prevented the attainment of that goal. Dr. Andreiko was also unsure if the problems due to variations in human anatomy could be overcome. No convincing countering evidence was produced by Ormco.

If an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement. Substantial doubt concerning the enablement of the invention was cast by the inventors in this case. The district court so concluded, and we have no reason to disagree. We thus affirm the summary judgment of nonenablement as to claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 1-5, 8-36, 41-44, 46-68, and 70-79 of the '444 patent because clear and convincing evidence establishes that a person of ordinary skill in the art did not and could not accomplish automatic computer determination of teeth finish positions based upon the Ormco patents' specification.

C. Cross-Appeal

Anticipation is a question of fact, but, in reviewing a grant of summary judgment of invalidity for anticipation, we determine *de novo* whether the evidence creates genuine issues of material fact that should have precluded summary judgment. *See Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001).

On cross-appeal, Align argues that the district court misconstrued the term "system" in claims 1-3 of the '548 patent in concluding that orthodontic appliances created by an iterative process could fulfill the requirements of that term. Align also argues that the district court erred in construing the language "marked to indicate their order of use" from claims 1 and 11 of the '548 patent because the court found that the information on order could be conveyed to the orthodontist rather than the patient. Finally, Align argues that there was no public use of Dr. Rains' devices, particularly as to the "marked" limitation.

In response, Ormco argues that our recent decision in *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299 (Fed. Cir. 2006) (*"Ormco I"*), requires that we affirm the district court's decision. Ormco also argues that the district court's construction of the "system" and "marking" language was correct and that the finding of anticipation by Dr. Rains' work should thus be affirmed. Finally, Ormco argues that the district court erred in its evaluation of Dr. Harrell's work, which also would have rendered Align's claims obvious.

We agree with Ormco that under the law of the case doctrine, the decision of this court in *Ormco I* controls the outcome of the cross-appeal here, and we therefore affirm the district court's summary judgment ruling that claims 1-3 and 11-13 of the '548 patent are invalid. "Under [the law of the case] doctrine a court adheres to a decision in a prior appeal in the same case unless one of three exceptional circumstances exist: (1) the evidence in a subsequent trial is substantially different; (2) controlling authority has since made a contrary decision of the law applicable

to the issues; or (3) the earlier ruling was clearly erroneous and would work a manifest injustice." *Gould, Inc. v. United States*, 67 F.3d 925, 930 (Fed. Cir. 1995). Because none of those exceptional circumstances exists in this case, the doctrine applies.

In *Ormco I*, this court decided that claims 10 and 17 of Align's '548 patent were invalid as obvious. Claim 10 is dependent on independent claim 1, and claim 17 is dependent on independent claim 11. Because claims 10 and 17 were found to have been obvious, the broader claims 1 and 11 must also have been obvious. Claims 2 and 3, and 12 and 13, of Align's '548 patent are also dependent on independent claims 1 and 11, respectively. Thus, their validity can only be sustained based upon the language of the dependent claims themselves. In *Ormco I*, this court decided that claims 2 and 3 of Align's '611 patent, which are dependent claims, were invalid as obvious. The language of claims 2 and 3 of the '611 patent is exactly the same as the language of claims 2 and 3 of the '548 patent. Furthermore, the language of claims 12 and 13 of the '548 patent differs from the language of claims 2 and 3 of the '611 patent only in that the word "method" replaces "system" and in that they depend on claims 11 and 12, respectively. Such a difference is not patentably significant. Therefore, claims 2 and 3 and 12 and 13 of the '548 patent must be invalid as obvious as well.

We thus affirm the district court's grant of summary judgment of invalidity as to claims 1-3 and 11-13 of the '548 patent.

CONCLUSION

For the reasons stated, we affirm the district court's grant of summary judgment of noninfringement and

nonenablement as to claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 1-5, 8-36, 41-44, 46-68, and 70-79 of the '444 patent. We reverse the district court's grant of summary judgment of noninfringement and nonenablement as to claims 37-40, 45, and 69 of the '444 patent and remand for further proceedings consistent with this opinion. Finally, we affirm the district court's grant of summary judgment of invalidity as to claims 1-3 and 11-13 of the '548 patent.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

United States Court Of Appeals
For The Federal Circuit

2006-1240, -1274

ORMCO CORPORATION
Plaintiff/Counterdefendant-Appellant,

and

ALLESEE ORTHODONTIC APPLIANCES, INC.,
Counterdefendant,

v.

ALIGN TECHNOLOGY, INC.,
Defendant/Counterclaimant-Cross Appellant.

O'MALLEY, *District Judge*,* concurring in part and dissenting in part.

I concur in the majority's decision that claims 37-40, 45, and 69 of the '444 patent do not require automatic computer determination of teeth finish positions, and that the law of the case doctrine bars Align's cross-appeal. I respectfully dissent, however, from those portions of the majority's decision that affirm the district court's grants of summary judgment to Align on the issues of non-infringement and non-enablement. I believe that the district court failed to construe properly the relevant claim terms, and improperly analyzed and shifted the burden of

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* Honorable Kathleen M. O'Malley, District Judge, United States District Court for the Northern District of Ohio, sitting by designation.

proof on the issue of enablement. I further believe that an insufficient record exists to support an attempt to correct the district court's omissions by construing the claims on appeal. I find further that the majority's decision, while acknowledging the need to construe the claims, improperly imports limitations from both the specifications and an ancestor patent into many of those claims. For these reasons, I would reverse and remand.

I.

Align's principal argument, implicitly accepted by the majority, is that neither the district court, nor this court on review, need begin the infringement analysis with the language of the claims. Instead, Align argues that an examination of the specification of the patents in suit and the prosecution history of an antecedent patent permits a court to find that the heart of Ormco's invention is the practice of automatically determining finish tooth positions and to compare the accused product to that finding, rather than to the claims of the governing patents. I disagree.

At the outset, it is apparent that the trial court improperly considered the question of infringement without actually construing the claim terms at issue. Indeed, the district court specifically stated that it, "was not interpreting the specific language of the claims to favor one side or another." *Ormco Corp. v. Align Tech., Inc.*, No. 03-cv-00016, slip op. n.1 (C.D. Cal. May 13, 2004).[1] Though this court has under-

[1] The district court cited *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1347 (Fed. Cir. 2004), as support for its claim construction approach. In *Microsoft*, however, contrary to the approach taken by the district court here, this court

taken claim construction in the first instance, it has also remanded cases for further construction in the absence of any meaningful claim construction by the district court. The court has rejected the assertion that, because it conducts a *de novo* review of claim construction, a district court's claim construction "does not matter" and the absence of a claim construction is not error. *Nazomi Commc'n, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1371 (Fed. Cir. 2005). In *Nazomi*, the court explained, in remanding for further claim construction, that "[t]his court's review of a district court's claim construction, albeit without deference, nonetheless is not an independent analysis in the first instance. Moreover, in order to perform such a review, this court must be furnished 'sufficient findings and reasoning to permit meaningful appellate scrutiny." *Id.* (citing *Gechter v. Davidson*, 116 F.3d 1454, 1458 (Fed. Cir. 1997)). The district court here has furnished this court with no such findings. *See also Shuffle Master, Inc. v. Vendingdata Corp.*, 163 Fed. Appx. 864, 86869 (Fed. Cir. 2005) ("While claim construction is a question of law, the district court's analysis is important to the process of claim construction, and in this context, as in others, we decline to construe the claim without the guidance of the district court's construction."); *Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1311 (Fed. Cir. 2003) (finding: "[i]n order to review the court's finding of non-infringement, we must know what meaning and scope the district court gave to the asserted claims"); *Graco, Inc. v. Binks Mfg. Co.*, 60 F.3d 785, 791 (Fed. Cir. 1995) (stating that the "entire omission of a claim construction analysis from

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turned to the specification and prosecution history only after an examination of the claim language. *See id.*

the opinion . . . provide[s] an independent basis for remand").

While I sympathize with the district court's desire to resolve the case before it without resort to the daunting task of construing ninety-two claims in four separate patents, a non-infringement decision which eschews the very exercise of claim construction is inconsistent with this court's repeated directives to district courts.[2] I believe, accordingly, that the district court's failure to construe the claim language in this case, standing alone, warrants remand.

II.

Rather than remand the matter, the majority chooses, instead, to conduct its own infringement analysis. It opens that analysis by recognizing that claim construction begins with the language of the claims themselves. In support, the majority cites *Phillips* and *Markman* for the truisms that, "the claims of a patent define the invention to which the patentee is entitled the right to exclude," and that, though claims, "must be read in view of the specification, of which they are a part," it is the language of the claims that is to be construed, not the specifica-

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[2] There are legitimate ways in which district courts can streamline the claim construction analysis when faced with myriad claims from multiple patents. District courts may choose, for instance, to construe only the independent claims of the various patents, or may direct the parties to identify the most representative claims for construction. In that way, the district court can provide guidance as to its construction of the most critical or oft-repeated claim terms and, thus, provide a roadmap with respect to the direction any additional claim construction might take. Employing strategies to streamline the claim construction process is fundamentally different, however, from avoiding the process altogether.

tion. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The majority, nevertheless, appears to ignore its own opening admonitions in the remainder of its opinion. First, the majority does not "begin" with the language of the claims. Indeed, it never actually tells us what word or words in the claims in suit it purports to construe. At best, after examining the specification of one of the patents in suit (but not its prosecution history), and the prosecution history of a patent which is not in suit, it backs into a form of claim construction by asserting that all of the claims address themselves to the practice of determining finish tooth positions. Nowhere, however, does the majority tell us *what* language is used in *which* claims to describe that practice, or why such language is in need of interpretation.

The majority concedes, as it must, that none of the claims in suit "expressly recite automatic control of the finish tooth positioning." Despite the absence of this language in the claims, however, the majority concludes that this unstated (and seemingly important) limitation is "what [the claims] mean."

In its analysis of the specification, the majority first cites to general statements in the Background and Summary of Invention sections of the patent where the inventors discuss the benefits of computer-assisted (*i.e.* automated) methods for designing orthodontic appliances, most particularly the greater accuracy that can be gained by reducing reliance on human decision-making. It then examines the preferred embodiments and concludes that those embodiments only contemplate human or operator input

into the process at the front end—*i.e.*, when the user first inputs the data into the computer for processing. From these portions of the specification, the majority concludes that the essence of Ormco's invention requires, "automatic determination of the finish positions of teeth without human adjustment of the final results." This exercise of attempting to glean the intended invention from sources other than the claims themselves is precisely what Align asked that we do. (*See* Appellee's Br., 36, 39 ("Ormco made it very clear in the specification . . . that *the very nature of its invention* was for automatic computer determination of the finish positions of teeth . . . ;" and "the statements Align drew from the specification and the file histories are admissions concerning *the fundamental nature of Ormco's invention*, not narrow statements concerning the meaning of some particular specific term.") (emphases in original).)

This court, however, has rejected a claim construction process based on the "essence" of an invention. *See, e.g., Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002) ("It is well settled that 'there is no legally recognizable or protected essential element, gist or heart of the invention in a combination patent.'") (citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961)). Indeed, this court has done so quite forcefully and quite recently. *See MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330-31 (Fed. Cir. 2007) ("We sympathize with the district court's choice, since we agree that [the feature] is an essential element of the invention . . . . However, we cannot endorse a construction analysis that does not identify 'a textual reference in the actual language of the claim with which to associate a proffered claim construction.'") (quoting *Johnson Worldwide Assocs., Inc. v. Zebco*

Corp., 175 F.3d 985, 990 (Fed. Cir. 1999)). Simply stated, "automatic determination of finish tooth positions without human adjustment of the final results" is a limitation that the majority has amalgamated from the specification of one of the patents in suit without reference to the specific language of *any* claim of *any* of the patents.

The court's recent decision in *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, 473 F.3d 1173 (Fed. Cir. 2006), counsels against this practice. In *Ventana*, the issue was the proper construction of the term "dispensing" in a patent claiming automated methods for staining microscope slides. *Ventana*, 473 F.3d at 1176. The district court construed "dispensing" to require "direct dispensing," because the embodiments in the specification involved direct dispensing (much as the district court here determined that processing, determining, and calculating orthodontic solutions require *automatic* processing, *automatic* determining, and *automatic* calculating). *Id.* at 1178. On appeal, Biogenex argued that the specification, when read in its entirety, would lead to the "inescapable conclusion" that the heart of the invention involved "direct dispensing," and that the specification implicitly defined the term "dispensing" to mean "direct dispensing." This court, in *Ventana*, rejected that narrowed construction of the claims, noting this court's previous repeated warnings against confining claims solely to disclosed embodiments. *Id.* at 1181 ("[While] the fact that the disclosed embodiments are limited can assist in interpreting claim language . . . [it] does not in and of itself mean that the method claims at issue are limited to the disclosed embodiments."); *see also Phillips*, 415 F.3d at 1323 (rejecting, "the contention that if a patent describes only a single embodiment, the claims of the

patent must be construed as being limited to that embodiment"). The court should do so again here.

As mentioned above, there are four separate patents in suit, the '444, the '861, the '243, and the '432. Ormco points to ninety-two claims in those patents which it claims Align has infringed, seventy-six of which are found in the '444 patent. By way of example, independent claim 1 of the '444 patent claims:

> A method for use in the orthodontic correction of malocclused teeth of a patient in accordance with the individual anatomy of the patient and a prescription of an orthodontic practitioner for treatment of the patient, the method comprising:
>
> generating data by scanning shapes of the teeth of a patient;
>
> displaying a graphic representation of the teeth of the patient with a computer from the generated data; and
>
> through an operator interacting with a computer located remote from the orthodontic practitioner, altering the graphic representation to arrange a plurality of the teeth in relation to each other in accordance with the prescription, to produce a digital model of a desired arrangement of the teeth of the patient that includes data of the shapes of a plurality of the teeth positioned relative to each other.

'444 patent col.67 l.57—col.68 l.6. Though this claim does not exclude operator involvement in the process and, indeed, *claims* the involvement of an operator in certain steps of the process, and though the claim never uses the term "automatically," the majority concludes that this claim, and virtually every other

claim in suit, claims a process that is "completely automatic" and allows for no skilled operator involvement. In short, the majority has: imported the terms "automatically" and "automated" from the specification to the claims; found that the terms "automatically" and "automated," when used in the specification, are the same terms (without a record of how one skilled in the art would construe those terms);[3] concluded that, in every instance, the words "automatically" and "automated" mean "completely automatically" or "completely automated;" found that, where a claim is silent on the issue, use of an operator is wholly precluded; and found that, where involvement of an operator is claimed, that operator cannot be skilled. Given the limited record in the trial court, I cannot find support either in the claims or in the record for these determinations.

In reaching these conclusions, moreover, the majority necessarily ignores those places in the claims where the addition of an automatic process *is* discussed. For instance, claim 4 of the '444 patent recites: "The method of claim 3 further comprising: generating machine code in response to the designed geometry; and transmitting the machine code to a manufacturing machine to *substantially* automati-

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[3] The absence of a record regarding how one of ordinary skill in the art would have understood the terms "automated" and "automatically" at the time the application was filed is particularly important. In fast-moving technologies, like the computer technology at issue here, words can mean vastly different things at different points in time. Thus, what we would consider to be meaningful advances in the use of computers in a particular process (i.e., injecting automation into a process previously done by hand) today could be far different from what one skilled in the art would understand was possible—and, thus, was novel—even a few years earlier.

cally operate the machine in accordance with the shapes of the plurality of teeth." '444 patent, col. 68, ll. 19-26 (emphasis added). Why would a claim use the phrase "substantially automatically operate the machine" if the inventors intended that *every* claim included a requirement that the machine be operated "completely" or "wholly" automatically? Who or what completes the "substantial" operation of the machine if not an operator? These kinds of questions emphasize the need for an assessment of the actual language used in the claims, rather than a construction of the invention that is reached *despite* that language.

Apparently recognizing the danger of counseling a district court to rely on language from the specification to the exclusion of language in the claims themselves, and recognizing that the statements in the specifications are less definitive than Align claims, the majority concedes that "standing alone" the statements in the specification may not be conclusive to show that the claims require completely "automatic determination of finish tooth positions." To support its construction of the invention, accordingly, the majority turns to the prosecution history of the '562 patent and finds that the doctrine of prosecution history disclaimer mandates the conclusion the majority reaches. This approach is similarly unavailing. *See Armament Sys. & Procedures, Inc. v. Monadnock Lifetime Prods.*, 168 F.3d 1319 (Table), 1998 WL 537746, at **3 (Fed. Cir. Aug. 7, 1998) (citing *Markman*, 52 F.3d at 980) (emphasis added) (noting that "Monadnock next argues that the prosecution history requires that the four-step process be read into claim 1 of the '297 patent. Again we disagree," and finding that "*any argument based on prosecution history must fail for the same reason as the specifica-*

tion argument: lack of textual support in the claim"); *id.* ("Accordingly, statements appearing in the file history of the patent are not sufficient to add entirely new limitations to a claim.").

Prosecution disclaimer requires a patentee to *clearly* and *unmistakably* disavow certain interpretations, and I find no such disavowal here. *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005) ("There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term."); *Omega Eng'g, Inc. v. Reytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). Importantly, while the quotations lifted from the '562 patent history do appear to support the majority's conclusion that the process contemplated in *that* potential invention was a highly automated one, that language was proffered to the examiner in connection with claims in that patent which do not share claim language with the majority of the claims at issue in this suit. The amendments were all made in response to the examiner's concerns regarding the formation of "ideal dental archforms," and the use of a computer to "derive . . . tooth finish positions . . . to place the teeth on the ideal dental archform." That process simply is not claimed in the '444 patent. The majority concedes this fact, but finds no limitations on the application of prosecution disclaimer posed by it. The majority cites *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999), and *Jonsson v. Stanley Works*, 903 F.2d 812, 818 (Fed. Cir. 1990), for the proposition that statements in the prosecution history of an ancestor patent are relevant as long as the patents in suit address the same general subject matter.

The court's more recent decisions, however, set forth a more restrictive rule—requiring common language or a linguistic "hook" among the claims before resort to a parent application's prosecution history is appropriate. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005) ("[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application."); *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1383 (Fed. Cir. 2003) ("Although a parent patent's prosecution history may inform the claim construction of its descendent . . . prosecution history is irrelevant to the meaning of [a] limitation [if] the two patents do not share the same claim language."); *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305-06 (Fed. Cir. 2001) (finding prosecution history of parent patents to be irrelevant where "there are no common claims in dispute"); *see also Alloc, Inc. v. Intl Trade Comm'n*, 342 F.3d 1361, 1381 (Fed. Cir. 2003) (Schall, J., dissenting) ("Statements . . . made during the prosecution of a parent application can only apply to continuation applications if the parent and child patents contain the same claim limitations."); *Serrano v. Telular Corp.*, 111 F.3d 1578, 1584 (Fed. Cir. 1997) (stating that "[t]he patentee's statement concerning whether the prior art discloses a 'send' signal means is relevant only to those claims which require the generation of such a signal, and those claims are not asserted here" and reasoning that "[a]lthough statements in a file history may of course be used to *explain and potentially limit* the meaning of claim limitations, . . . [they] *cannot* be used to *add an entirely new limitation to the claim*") (emphases added). Here, however, neither Align, the district

court, nor the majority has identified any linguistic hooks between the '562 and '444 patents.[4]

Again, the court's recent decision in *Ventana* provides guidance on the issue. In *Ventana*, this court rejected the argument that, in prosecuting an ancestor patent, the applicants disclaimed certain devices that could not dispense reagent "directly to a sample," explaining that: "[b]ecause *claims 1 and 5* of the [descendent] patent use different *claim language* . . . the alleged disclaimer [of the ancestor patent] . . . does not apply to the asserted *claims* of the [descendent] patent." *Ventana*, 473 F.3d at 1182 (emphases added, citations omitted) (also stating that the court examines a patent's prosecution history to "determine whether the inventor disclaimed a particular interpretation of a claim term during the prosecution of the patent in suit or . . . of an ancestor application. *But the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language.*") (emphasis added). In *Ventana*, the court correctly examined the specific language of the claims, not the general subject matter of the invention, when it looked to the prosecution history of the ancestor patents. Thus, in *Ventana*, although the claims of the descendent patent involved similar subject matter and, indeed, shared some common language, this court nonetheless held that critically different language between *the claims* precluded the use of disclaiming statements made while prosecuting the ancestor patent to limit the claims of the descendent patent. In sum, the only

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[4] Ormco concedes that there are linguistic hooks to some claims in some of the patents, particularly in the '432. This appears true, however, only as to a minority of the ninety-two asserted claims.

potential relevance of the '562 prosecution in this case would be to illuminate the construction of a word or linguistic hook shared by the patents in suit.[5] *Invitrogen*, 429 F.3d at 1078 (stating: "a prosecution disclaimer or prosecution history estoppel argument, . . . falters on the principle that the prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application"). Align has not provided those hooks.

III.

The district court's rulings regarding enablement were based wholly upon this flawed claim construction and, therefore, are unsustainable as well. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004) (stating: "an enablement inquiry typically begins with a construction of the claims"). Specifically, the district court found that, because he believed the patent intended a wholly automatic process, and he did not find that the inventors had ever successfully performed the process in the absence of any operator involvement, the invention was not enabled by the patent. Because, as discussed above, the first of the district court's premises was based on a flawed infringement analysis, its non-enablement conclusion must also be reversed. There are, moreover, additional flaws with the trial court's analysis of the enablement of Ormco's patents that should be noted.

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[5] Ormco also correctly points out that claims 1 and 37 of the '444 patent were allowed in the first office action and that those claims of the '444 patent that were rejected over Lemchen were allowed after Ormco made amendments having nothing to do with automatically determining the finish positions of teeth. Thus, the majority's present application of the '562 history, to the exclusion of the '444's own prosecution history, would seem to render the '444's prosecution meaningless.

An enablement inquiry turns on whether the specification of a challenged patent: "provide[s] sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1337 (Fed. Cir. 2005) (citations omitted). "Furthermore, '[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.'" *Id.* (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir.1988)). "Some of these considerations, commonly referred to as 'the *Wands* factors,' include '(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.'" *Id.* (quoting *Wands*, 858 F.2d at 737).

Here, however, the district court did not examine the specifications to determine whether one of ordinary skill in the art could make and use the invention without undue experimentation. Indeed, there is no indication that the district court considered any of the factors enumerated in *Wands*. *Ormco Corp. v. Align Tech., Inc.*, No. 03-cv-00016, slip op. at 3-7 (C.D. Cal. Aug. 23, 2004). Instead, Align only produced, and the district court only focused on, evidence of whether Ormco had perfected a commercially successful version of the invention. Commercial success, however, is not determinative of enablement. *See CMFT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003) ("Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially

viable embodiment absent a claim limitation to that effect.").[6] I believe, therefore, that the district court's limited, improper examination of the enablement issue could not have supported summary judgment in Align's favor on this issue.

IV.

For the foregoing reasons, I cannot endorse the district court's infringement analysis or its analysis of enablement, and cannot agree with the majority's construction of the claims in the face of an inadequate record upon which to do so. While it ultimately may be true that some language of some of the claims in suit may require the very "construction" the district court and the majority afford them (because the specification *is* critical to a proper claim construction process, and a parent application *does* meaningfully inform construction of similar claim language in later patents), it is impossible to tell from the current record whether, and to what extent, that fact is true. It appears, moreover, that, as to many, if not most, of the critical claims at issue, the construction the majority endorses is simply not supported by a proper application of this court's precedents. Accordingly, I would reverse the district court's grants of summary judgment, and remand with direction that the claim language at issue be construed and that a record supporting that construction be developed.

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[6] It is also apparent that the district court improperly shifted the burden of proof to Ormco by requiring it to produce corroborated testimony on the issue of enablement. "[C]orroboration is required of any witness whose testimony alone is asserted *to invalidate a patent*, regardless of his or her level of interest." *Finnigan Corp. v. Intl Trade Comm'n*, 180 F.3d 1354, 1369 (Fed. Cir. 1999) (emphasis added). Here, Align, not Ormco, sought invalidation of the patent.

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

[Filed MAY 13, 2004]

Case No. SA CV 03-16-GLT (ANx)

ORMCO CORPORATION,
Plaintiff,

vs.

ALIGN TECHNOLOGY, INC.,
Defendant.

ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT, DEFENDANT'S MOTION TO LIMIT CLAIMS, AND PLAINTIFF'S MOTION FOR A MARKMAN DETERMINATION

Defendant's motion for summary judgment is GRANTED. Defendant's motion to limit the number of claims asserted and Plaintiff's motion for a Markman determination are MOOT.

I. BACKGROUND

Plaintiff Ormco Corporation owns four patents which are directed to computer-aided orthodontics. Plaintiff brought this suit against Defendant Align Technology, Inc., alleging Align's Invisalign System infringes these patents. Defendant moves for summary judgment of non-infringement. Alternatively,

Defendant moves to limit the number of asserted claims.

Plaintiff Ormco moves for a Markman determination.

II. DISCUSSION

Defendant argues the scope of each asserted claim is limited by the specification and by Ormco's disclaimers during prosecution. *See Microsoft Corp. v. Multi-Tech Sys.*, 357 F.3d 1340, 1347 (Fed. Cir. 2004) ("When the specification 'makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.' *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). 'A patentee may also limit the scope of the claims by disclaiming a particular interpretation during prosecution.' *Biodex Corp. v. Loredan Biomed., Inc.*, 946 F.2d 850, 862 (Fed. Cir. 1991).").

Defendant argues Plaintiff's patents are limited to automatic computer determination of treatment positions and the automatic computer design of an orthodontic appliance. Defendant contends Ormco cannot claim its patents cover a system requiring skilled human operators, such as Align's Invisalign System.

A. The Claims[1]

"[C]laim construction . . . begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). The proper construction of the claims of the patent at issue is a question of law for the Court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The language of most of the asserted claims requires either: (1) automatic determination of tooth positions and automatic design of an orthodontic appliance or (2) a process that could be completed automatically or manually with an operator. The exception is claim 1 of the '444 Patent, which refers specifically to an "operator interacting with a computer." The claim language is included in Appendix 1 of this decision.

B. The Specifications

The statements in the specifications limit Ormco's claims to automatic design and manufacture of

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[1] The Court adopts an approach to claim construction which is in line with recent Federal Circuit authority. *See Microsoft Corp. v. Multi-Tech Sys.*, 357 F.3d 1340, 1347 (Fed. Cir. 2004). Plaintiff argues Defendant's motion must fail because the motion did not identify the claim limitations specifically. In fact, Defendant attached the claims to its motion as an exhibit.

Plaintiff also moves to strike the sections of Defendant's reply that point to specific claim language, or in the alternative, it moves for additional briefing on this issue. The motion to strike or for additional briefing is DENIED. There is no need to strike or allow arguments in response to Defendant's reply section because Defendant is only pointing to specific language in the claims which were already before the Court. The Court is not interpreting the specific language of the claims to favor one side or the other. The claim language is referenced to establish the point that the claimed action could be performed manually or automatically.

orthodontic appliances. *SciMed Life Sys., Inc., supra,* 242 F.3d at 1341 ("When the specification 'makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.'").

The Summary of Invention in each patent decribes a primary objective of Ormco's invention as providing "a practical, reliable and efficient custom appliance automated design and manufacturing system and methods of automatically designing custom orthodontic appliances and treating patients therewith." (emphasis added). They further describe:

> In accordance with the preferred embodiment of the present invention, there is provided a computerized system and method with which finish positions of the teeth of a patient are derived from digitized information of anatomical shapes of the patient's mouth, an orthodontic appliance is automatically designed from the digitized shape information, and the derived tooth finish positions . . . (emphasis added).

The Field of Invention Statement of the '432, '243 and '861 Patents states:

> The present invention relates to the design, manufacture and use of orthodontic appliances for the straightening of teeth, and more particularly, to the automated design, manufacture and use of custom orthodontic appliances based [on] individual patient anatomy and to the diagnosis of patients therefor and the treatment of patients therewith. (emphasis added).

The abstract of the '861 Patent states:

> A system and method by which an orthodontic appliance is automatically designed and manufactured . . . A computer is programmed to construct archforms and calculate finish positions of the teeth, then to design an appliance. . . . (emphasis added).

Ormco argues there are several portions of the specification which refer to operator involvement. Those passages will not be recited again here. These sections only refer to operator input of information and do not describe a skilled operator making decisions about the final positions of the teeth.

C. The Prosecution History

A prosecution history does not limit any claim terms unless the prosecution history is clear. *See York Prods. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1575 (Fed. Cir. 1996) ("[A] patent applicant only limits claims during prosecution by clearly disavowing claim coverage."). The Court holds the prosecution history is clear that the scope of Ormco's claims are limited to automatic computer determination of the finish positions of teeth. *See Biodex Corp., supra*, 949 F.2d at 862 ("A patentee may also limit the scope of the claims by disclaiming a particular interpretation during prosecution.").

In an Office Action dated September 13, 1993, the Patent Office rejected each of the claims in the application leading to the '562 Patent.[2] The claims

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[2] All of the patents-in-suit are related to the '562 Patent. "[P]rosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1333 (Fed. Cir. 2003).

were rejected in part based on a prior art patent by Lemchen. In order to overcome this rejection, Ormco made a number of statements to the PTO.

1. Statements Made By Ormco In Its March 16, 1994 Response

Ormco acknowledges the Lemchen prior art involved a human operator manipulating tooth images:

> Using such a CAD program in a conventional manner, such as Lemchen describes, an operator would manipulate the tooth images to provide the desired occlusion. This would presumably involve some decision making by the operator. As the operator manipulates the images, the computer, under the control of the conventional CAD program, would perform calculations that would generate data of the tooth movements made by the operator and thus of the finish positions of the teeth.

Ormco further emphasizes the reliance on human decision making:

> The Lemchen patent relies, to produce the calculations, on the conventional calculation techniques employed in generalized CAD software. This in turn relies on a user interactive interface by which an operator contributes human decision making powers to manipulate images until the operator is satisfied that finish tooth position criteria have been met. The Lemchen method provides a computerized way to achieve bracket placement to precisely position patient teeth to the finish positions that the operator, with the aid of the CAD computer, has calculated. However, with conventional CAD programs, the reliance on human decision making is heavy, and

> rigorous fully automated arrival at tooth finish positions is lacking.

Ormco next clarifies Lemchen does not involve algorithms to automate the orthodontic appliance design:

> While a computer operator might pictorially be able to manipulate tooth images toward finish positions that provide an orthodontically acceptable occlusion and satisfy aesthetic considerations, no mathematically definable algorithms or process is set forth in the Lemchen patent to define how any of the thousands of digitized points on each of the respective teeth are to be related to the thousands of points on any of the other teeth to facilitate more fully automated orthodontic appliance design.

Ormco describes its invention as collecting digital information "which is sufficient to automatically design and manufacture an orthodontic appliance." Ormco also stated it is a "computerized system with the intelligence to decide for itself the best finish positions for the teeth." Finally, Ormco wrote "once the digitized data is input into a computer, no further orthodontic decision making is required until after the system produces the custom appliance. . . ."

2. Statements Made By Michael W. Scott, DDS, MSD To The Patent Office On Behalf Of Ormco

In support of its attempt to overcome the prior art, Ormco submitted a declaration to by Michael W. Scott, DDS, MSD, to the PTO on March 16, 1994. Dr. Scott stated:

> The method described . . . in their patent application is the most complete and fully auto-

mated method of orthodontic appliance manufacture ever proposed.[3] Particularly important contributions of the applicants are the features that make possible the automated custom design of the appliance, and particularly that enable a computer to determine automatically the best finish positions for the patient's teeth.[4] Applicants digitize data of tooth and jaw shape and then derive an "ideal dental archform." From the ideal dental archform, applicants use the computer to automatically and precisely derive the optimum finish positions, according to their sophisticated criteria, to which the patient's teeth are to be moved by orthodontic treatment. In applicant's overall method, it is a computer, not an orthodontist or an orthodontically skilled computer operator, that makes the decision on the finish positions in which the teeth are to be placed. Applicants' method then automatically designs an orthodontic appliance. . . . (emphasis added).

3. Statements Regarding the Abandoned 07/775,589 Application

Although Plaintiffs abandoned this application in the chain leading to the '562 Patent, it specifically excludes a system which involves human decision making:

> The applicants of the present application set forth . . . further advances in the art by

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[3] In an Office Action of May 24, 1994, the PTO again rejected Ormco's claims and Ormco responded with an Amendment on September 26, 1994. In this amendment, Ormco adopted this statement of Dr. Scott as a factual statement.

[4] Ormco also adopted this statement in its September 26th Amendment.

> introducing certain automatic design making capabilities in automated orthodontic appliance design. As a result, digitized tooth shape data is reduced to a form that facilitates the direct calculation, without operator intervention or human decision making steps, which leads in the geometry and placement of an orthodontic appliance that inherently results in the proper positioning of teeth to orthodontically preferable finish positions, without the need for either an operator or an orthodontist to consciously decide the specific tooth finish positions. (emphasis added).

4. Statements Regarding the '432 Patent

In an Office Action of June 27, 1994, the Patent Office rejected the pending claims of the '432 Patent. Ormco filed an Amendment on September 27, 1994, stating "the present invention is directed to the concept of automatically designing and producing a orthodontic archwire. . . ." The Amendment also stated:

> The claims rather provide a process that directly or indirectly senses data representing shapes from the patient's mouth, sorts or manipulates and compares tooth or jaw shape data to determine a desired orthodontic result, to design an appliance that achieves the result, and to manufacture an appliance according to the design for mounting on the teeth of the patient to achieve the orthodontic result.

D. Non-Infringement Analysis

Summary judgment is proper if "there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law."

Fed.R.Civ.Pro. 56(c). A fact is material if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

Most of the claims Ormco asserts against Align include language explicitly requiring automatic design and manufacture or requiring a process that could be completed automatically or manually with an operator. However, as discussed above, the specification and prosecution history limit these claim terms to automatic processes.

Defendant argues Ormco has no valid infringement claims because Align relies on skilled operators—not computers—to manipulate images and make decisions about where and how the teeth should move. Defendant supports this argument by providing evidence the Invisalign process does not use computers to calculate the proper finish positions of the teeth.

Plaintiff argues genuine factual disputes preclude summary judgment. The Court finds there are no triable issues.

Plaintiff offers evidence to support the theory the Invisalign process calculates intermediate positions of the teeth, which, they assert, amounts to automatic determination of final teeth positions. The intermediate positions are steps to final positions, and they are not equivalent. There is no triable issue whether determination of intermediate positions infringes Ormoco's claims.

Plaintiff also contends the Invisalign process calculates tooth positions as part of its collision detection software. Defendant argues this process is computer

assisted design, not automatic determination of final teeth positions. Align's Director of System Engineering, Andrew Beers, submits a declaration explaining the operators determine intermediate treatment steps in order to achieve the proper finish positions. The operators use the computer to detect collisions that occur when the teeth move from their initial to final positions. If there are collisions, the operators, not the computer, adjust the treatment plan. Because the collision detection software does not automatically determine teeth positions, there is no triable issue whether this process infringes on Ormco's patents.

Plaintiff argues Align performs automatic design of final teeth positions with FiPos, a "plug-in" software module. Plaintiff provides evidence of Align's Software Development Plan for FiPos2, dated February 5, 2001, which describes the goal of the project is "to set up the treated tooth position automatically." By itself, this evidence does not create a triable issue for damages because Ormco has no right to seek damages for any time before the filing of this suit on January 6, 2003.[5]

Plaintiff submits evidence showing FiPos source code was included with the source code produced on October 7, 2003 for Treat version 3.1, and argues this

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[5] Ormco originally filed an infringement action against Align in January 2000. Ormco and Align agreed to defer the litigation until after Ormco's additional patent issued. As part of the Agreement, Ormco agreed not to "seek any damages . . . because of any infringement occurring before the date of commencement of said subsequent action." Ormco does not dispute it is unable to collect damages for activity before January 6, 2003.

The Court will not address the other evidence Ormco provides which relates to activity before January 2003.

suggests FiPos may have been used with that release. Treat is the software program used by Align to implement the Invisalign process. Mr. Beers explains unused source code is not removed, it is simply not compiled. Mr. Beers also states he "instructed Mr. DeBruin (counsel for Ormco) and Mr. Klausner (Ormco's expert) how to verify, from looking at the copies of the source code that we produced, that certain plug-ins (such as FiPos) were not compiled in Treat." Plaintiff has not submitted evidence Align used FiPos in the Treat software. The source code itself does support the conclusion FiPos was used, and it does not create a triable issue.

Plaintiff submits evidence showing Align's strategic plan documents include FiPos in the list of ongoing projects for the year 2003. There is a document from May 2003 which refers to "Automated FiPos" and "Highly Automatic FiPos" in a section entitled "Treat Automation" under the broader heading "Invisalign Principles." There is a document from April 2003 entitled "Software Subgroup Meeting Summary," which includes "Automatic FiPos" as a "Target Feature" in Phase 1 of Automated Treatment Planning. Andrew Beers stated in his declaration:

> While Align continues to consider FiPos as a possible development project sometime in the future, it has not reinitiated any development efforts to resurrect the FiPos project. Align does not currently and has not since approximately 2001 used or attempted to develop FiPos.

Align's strategic plan documents do not show FiPos was used and do not create a triable issue for future infringement. *See Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 765 (Fed. Cir. 1990) (no jurisdiction over threatened future infringement).

III. DISPOSITION

Defendant's motion for summary judgment is GRANTED. Defendant's motion to limit the number of claims asserted and Plaintiff's motion for a Markman determination are MOOT.

DATED: May 11, 2004

/s/ Gary L. Taylor
GARY L. TAYLOR
UNITED STATES DISTRICT JUDGE

APPENDIX 1

Ormco asserts infringement of claims 1, 9, and 10 of U.S. Patent No. 5,447,432 (" '432"). Claim 9 and 10 are dependant and do not need to be separately addressed. Claim 1 refers to "processing the digitized tooth shape data . . . , producing desired tooth position signals . . . , [and] calculating . . . tooth interconnecting arcuate geometry."

Ormco asserts infringement of claims 1 and 2 of U.S. Patent No. 5,683,243 (" '243"). Claim 2 is dependant. Claim 1 includes "a computer programmed to automatically derive a dental archform for the individual patient, to calculate finish positions of the teeth of the patient in relation to the archform, to calculate a custom orthodontic appliance design. . . ."

Ormco asserts infringement of claims 1, 3, 4, 9-12 and 16-18 of U.S. Patent No. 6,244,861 (" '861"). Claims 3, 4, 9-12 and 16-17 depend or multiply from claim 1. Claim 1 speaks to "determining treatment positions of the teeth on a dental arch . . ." and "processing in a computer the generated data and thereby designing a custom orthodontic appliance. . . ." Claim 18 refers to "deriving a dental archform from the digitized anatomical shape data . . ." and "deriving, on the computer, post-appliance positions for the teeth. . . ."

Ormco asserts infringement of claims 1-5 and 8-79 of U.S. Patent No. 6,616,444 (" '444"). Claims 1, 10, 18, 23, 30, 37, 45, 46, 54, 69 and 70 are independent. Claim 1 refers to "through an operator interacting with a computer. . . , altering the graphic representation to arrange a plurality of the teeth in relation to each other in accordance with the prescription, to produce a digital model of a desired

arrangement of the teeth. . . ." Claim 10 refers to "communicating the digitized data to a computer programmed to apply at least some automated tooth position criteria to produce a digital model of the teeth of the scanned shapes in desired positions." Claim 18 refers to "inputting tooth shape information into a computer that is . . . programmed to select geometric parameters on the patient's teeth from the digitized data by operator-interaction and to produce a digital model of the teeth in desired positions. . . ." Claim 23 refers to "transmitting the digital information to a computer configured for defining geometry of a custom orthodontic appliance. . . ." Claim 30 refers to "deriving an occlusion for the patient based on the received digital information and the individual anatomy of the patient on a computer. . . ." Claim 46 refers to a computer "configured for deriving custom geometry of an appliance for carrying out treatment of the patient in response to data entered by the practitioner. . . ." Claim 54 refers to "a computer thereat configured for digitally defining therewith positions to which to move the patient's teeth. . . ." Claim 70 refers to "determining with a computer an occlusion. . . ." Defendant does not argue claims 37-40, 45 or 69 of the '444 Patent contain language requiring either manual or automatic operation.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

[Filed OCT. 24, 2007]

2006-1240, -1274

ORMCO CORPORATION,
Plaintiff/Counterdefendant
Appellant,

and

ALLESEE ORTHODONTIC APPLIANCES, INC.,
Counterdefendant,

v.

ALIGN TECHNOLOGY, INC.,
Defendant/Counterclaimant
Cross Appellant.

ORDER

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 31, 2007.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 10/24/2007

cc: David L. DeBruin
Daniel J. Furniss

ORMCO CORPORATION V ALIGN TECH, 2006-1240,-1274
(DCT - 8:03-CV-00016)

This action comes before the Court on the pleadings and proceedings of record and it has been represented to the Court that Ormco and AOA and Align have agreed to a settlement of all issues remaining for trial or otherwise the subject of pending motions, pursuant to a Settlement Agreement.

WHEREFORE, the plaintiff, defendant and counterdefendants Stipulate as follows:

1. This Court has personal jurisdiction over the parties and the subject matter of this action, including the enforcement of the Settlement Agreement entered among the parties.

2. Pursuant to the Orders previously entered in this case, judgment is entered as follows:

a. This Court has subject matter jurisdiction over this matter;

b. The asserted Claims 10 and 17 of Align's U.S. Patent No. 6,398,548 and Claims 1-3 and 7 of Align's U.S. Patent No. 6,554,611 are valid and infringed;

c. The asserted Claims 1-3 and 11-13 of Align's U.S. Patent No. 6,398,548 are invalid;

d. The asserted claims of Align's U.S. Patent No. 6,398,548 and Align's U.S. Patent No. 6,554,611 are not unenforceable;

e. The asserted claims of Align's U.S. Patent No. 6,398,548 and Align's U.S. Patent No. 6,554,611 were not willfully infringed by Ormco or AOA;

f. The asserted claims of Ormco's U.S. Patent Nos. 5,683,243, 5,447,432, 6,244,861 and 6,616,444 are not infringed by Align, and

g. The asserted claims of Ormco's U.S. Patent Nos. 5,683,243, 5,447,432, 6,244,861 and 6,616,444 are invalid for lack of enablement.

3. Pursuant to the terms and conditions of the Settlement Agreement entered between Ormco and AOA and Align, the issues of past damages, willfulness and attorneys fees as they relate to Align's allegations of infringement of its patents have been settled. The Settlement Agreement and this Order do not affect, and the parties retain all rights to (1) Ormco and AOA' s currently pending appeal; (2) any appeal by Ormco of the decisions and orders relating to Ormco's patents; or (3) any appeal by Align of the orders relating to its patents.

4. Entry of final judgment on all issues in this case is appropriate.

5. Each party shall bear its own costs and attorneys' fees with respect to Align's allegations of infringement of its patents, except that Ormco reserves the right to seek costs and/or attorneys' fees in the event that Align's patents are ultimately determined to be unenforceable due to inequitable conduct. Applications for costs and/or attorneys' fees in regard to Ormco's allegations of infringement of its patents shall be made no earlier than a final decision on appeal of those issues and shall be due not later than thirty days after the resolution of Ormco's appeal of the findings of non-infringement and invalidity, or at such later time as the Court may order if the issues are remanded to the Court for further proceedings after appeal.

AGREED TO AND ACCEPTED BY:

DATED: February 2, 2006

Respectfully submitted,

MICHAEL, BEST & FRIEDRICH, LLP

By: /s/ Richard H. Marschall
DAVID L. DE BRUIN
RICHARD H. MARSCHALL
CHARLES J. CRUEGER
and
MITCHELL SILBERBERG & KNUPP LLP
THOMAS P. LAMBERT
KARIN G. PAGNANELLI

Attorneys for Plaintiff and Counterdefendants, ORMCO CORPORATION and ALLESEE ORTHODONTIC APPLIANCES, INC.

DATED: February 2, 2006

TOWNSEND & TOWNSEND & CREW LLP
By: /s/ Annie M. Rogaski
DANIEL J. FURNISS
GARY H. RITCHEY
ANNIE M. ROGASKI
SUSAN M. SPAETH

Attorneys for Defendant and Counterclaimant ALIGN TECHNOLOGY, INC.

[PROPOSED] FINAL JUDGMENT

With the consent of plaintiff, defendant and counterdefendants, it is hereby finally ORDERED, ADJUDGED and DECREED as follows:

1. This Court has personal jurisdiction over the parties and the subject matter of this action, including the enforcement of the Settlement Agreement entered among the parties.

2. Pursuant to the Orders previously entered in this case, judgment is entered as follows:

a. This Court has subject matter jurisdiction over this matter;

b. The asserted Claims 10 and 17 of Align's U.S. Patent No. 6,398,548 and Claims 1-3 and 7 of Align's U.S. Patent No. 6,554,611 are valid and infringed;

c. The asserted Claims 1-3 and 11-13 of Align's U.S. Patent No. 6,398,548 are invalid;

d. The asserted claims of Align's U.S. Patent No. 6,398,548 and Align's U.S. Patent No. 6,554,611 are not unenforceable;

e. The asserted claims of Align's U.S. Patent No. 6,398,548 and Align's U.S: Patent No. 6,554,611 were not willfully infringed by Ormco or AOA;

f. The asserted claims of Ormco's U.S. Patent Nos. 5,683,243, 5,447,432, 6,244,861 and 6,616,444 are not infringed by Align, and

g. The asserted claims of Ormco's U.S. Patent Nos. 5,683,243, 5,447,432, 6,244,861 and 6,616,444 are invalid for lack of enablement.

3. The issues of past damages, willfulness and attorneys fees as they relate to Align's allegations of infringement of its patents have been settled. The Settlement Agreement and this Order do not affect, and the parties retain all rights to (1) Ormco and AOA's currently pending appeal; (2) any appeal by Ormco of the decisions and orders relating to Ormco's patents; or (3) any appeal by Align of the orders relating to its patents.

4. Entry of final judgment on all issues in this case is appropriate.

5. Each party shall bear its own costs and attorneys' fees with respect to Align's allegations of infringement of its patents, except that Ormco reserves the right to seek costs and/or attorneys' fees in the event that Align's patents are ultimately determined to be unenforceable due to inequitable conduct. Applications for costs and/or attorneys' fees in regard to Ormco's allegations of infringement of its patents shall be made no earlier than a final decision on appeal of those issues and shall be due not later than thirty days after the resolution of Ormco's appeal of the findings of non-infringement and invalidity, or at such later time as the Court may order if the issues are remanded to the Court for further proceedings after appeal.

SO ORDERED:

Dated: Feb. 6, 2006

/s/ Christina A. Snyder
The Honorable A. Christina Snyder
United States District Court Judge

APPENDIX E

What is claimed is:

1. A method for use in the orthodontic correction of malocclused teeth of a patient in accordance with the individual anatomy of the patient and a prescription of an orthodontic practitioner for treatment of the patient, the method comprising: generating data by scanning shapes of the teeth of a patient; displaying a graphic representation of the teeth of the patient with a computer from the generated data; and through an operator interacting with a computer located remote from the orthodontic practitioner, altering the graphic representation to arrange a plurality of the teeth in relation to each other in accordance with the prescription, to produce a digital model of a desired arrangement of the teeth of the patient that includes data of the shapes of a plurality of the teeth positioned relative to each other.

2. The method of claim 1 further comprising: the interacting being by an operator other than the orthodontic practitioner and is at the location remote from that of the orthodontic practitioner; and transmitting the generated data to the operator at the remote location for display at the remote location.

3. The method of claim 1 further comprising: designing geometry with a computer, based on the relatively positioned shapes of the plurality of teeth, for use in the manufacture of an orthodontic appliance for treatment of the patient to move the teeth of the patient to the desired arrangement.

4. The method of claim 3 further comprising: generating machine code in response to the designed geometry; and transmitting the machine code to a manufacturing machine to substantially automatic-

ally operate the machine in accordance with the shapes of the plurality of teeth.

5. The method of claim 4 further comprising: operating the manufacturing machine in accordance with the machine code to shape surfaces that conform to at least portions of the shapes of the teeth of the patient.

6. The method of claim 5 wherein: the operating of the machine includes manufacturing cavities each bounded by at least one of the shapes for fitting on the crown of at least one of the teeth of the patient.

7. The method of claim 6 wherein: the manufacturing includes manufacturing an orthodontic archwire and a plurality of orthodontic brackets having geometries that cooperate to move the teeth of the patient to the desired arrangement; and the method further comprises providing a plurality of bracket positioning jigs, each having one of the cavities formed therein that is bounded by one of the shapes, for locating a bracket on the crown of one of the teeth of the patient.

8. The method of claim 1 wherein: the generating of the data by scanning shapes of the teeth of a patient includes scanning the shapes directly from the teeth in the mouth of the patient.

9. The method of claim 1 wherein: the generating of the data by scanning shapes of the teeth of a patient includes scanning the shapes indirectly from a model of the teeth of the patient.

10. A method for use in the orthodontic correction of malocclused teeth in accordance with the individual anatomy of the patient and an orthodontic prescription for treatment of the patient, the method

comprising: scanning shapes of the teeth of the patient and digitizing data of the scanned shapes; communicating the digitized data to a computer programmed to apply at least some automated tooth position criteria to produce a digital model of the teeth of the scanned shapes in desired positions, and generating a 3-D digital model of the patient's teeth in the desired positions based on the digitized data and in accordance with the prescription; and generating machine code to operate a machine to form tooth shapes in accordance with the digital model.

11. The method of claim 10 further comprising: manufacturing a custom orthodontic appliance having at least one 3-D surface conforming to the formed tooth shapes.

12. The method of claim 10 further comprising: generating the 3-D digital model of the patient's teeth, in response to the digitized data, representing a plurality of the teeth of the patient in desired post-treatment positions.

13. The method of claim 10 further comprising: producing the digital model of the teeth in desired positions by the interaction of an operator with the computer, and generating, through operator interaction with the computer, the 3-D digital model of the patient's teeth in the desired positions based on the digitized data and in accordance with the prescription.

14. The method of claim 13 wherein: the communicating of the digitized data to the computer includes communicating the information to a computer that is configured to respond to operator-selected geometric parameters on the patient's teeth

and to produce the digital model of the teeth in desired positions based on the selected parameters.

15. The method of claim 13 wherein: the communicating of the digitized data to the computer includes communicating the information to a computer programmed to accept operator selected geometric parameters on the patient's teeth and to calculate a digital model of an occlusion of the teeth of the patient in desired positions based on the selected parameters.

16. The method of claim 13 further comprising: selecting geometric parameters on the patient's teeth by operator-interaction with the computer; and calculating a digital model of the teeth in desired positions based on the selected parameters.

17. The method of claim 13 further comprising: selecting geometric parameters on the patient's teeth by operator-interaction with the computer; and calculating a digital model of an occlusion of the teeth of the patient in desired positions based on the selected parameters.

18. A method for use in the orthodontic correction of malocclused teeth in accordance with individual anatomy of the patient and an orthodontic prescription for orthodontic treatment of the patient by a practitioner, the method comprising: scanning shapes of the teeth of the patient; digitizing data of the scanned shapes; inputting tooth shape information into a computer that is remote from the practitioner and is programmed to select geometric parameters on the patient's teeth from the digitized data by operator-interaction and to produce a digital model of the teeth in desired positions based on the selected parameters.

19. The method of claim 18 further comprising: providing to the patient a custom orthodontic appliance having surfaces conforming to the shapes of the teeth of the patient and formed in response to machine code in accordance with the digital model.

20. The method of claim 18 wherein: the shapes of the teeth are scanned and the data is digitized at the site of the treating practitioner and the tooth shape information is transmitted in digital form to the computer remote from the treating practitioner.

21. The method of claim 18 wherein: the shapes of the teeth are scanned and the data is digitized remote from the treating practitioner.

22. The method of claim 18 wherein: the tooth shape information is communicated by transmitting a physical model of the teeth of the patient from the treating practitioner; and the shapes of the teeth are scanned and the data is digitized from the physical model remote from the treating practitioner.

23. A method of providing a custom orthodontic appliance for orthodontic treatment of a patient by a practitioner, the method comprising: generating digital information of 3-D tooth shape geometry of an orthodontic patient; transmitting the digital information to a computer remote from the practitioner and configured for defining geometry of a custom orthodontic appliance; and receiving in digital form geometry defined with the computer at a manufacturing machine configured to operate in response to the defined geometry for use in the manufacture of the custom orthodontic appliance having surfaces conforming to the 3-D tooth shape geometry.

24. The method of claim 23 further comprising: manufacturing the custom orthodontic appliance having the derived geometry.

25. The method of claim 23 further comprising: designing the custom orthodontic appliance with the computer.

26. The method of claim 23 further comprising: designing the custom orthodontic appliance with the computer; and manufacturing the custom orthodontic appliance as so designed.

27. The method of claim 23 further comprising: designing the custom orthodontic appliance with the computer, the designing including deriving desired positions of the patient's teeth from the digital information and basing the designing of the appliance on the derived desired positions.

28. The method of claim 23 wherein: the digital information includes data of the shapes of the teeth of the patient.

29. The method of claim 23 wherein: the digital information includes a prescription for the orthodontic treatment of the teeth of the patient.

30. A method of facilitating the custom orthodontic treatment of a patient comprising: receiving digital information concerning the treatment of an orthodontic patient from an orthodontic practitioner via a computer at the site of the practitioner; and deriving an occlusion for the patient based on the received digital information and the individual anatomy of the patient on a computer at a location remote from the office of the orthodontic practitioner.

31. The method of claim 30 further comprising: communicating digital information to the orthodontic practitioner relating to the derived occlusion.

32. The method of claim 30 further comprising: designing geometry of a custom orthodontic appliance on a computer at a location remote from the office of the orthodontic practitioner, that is based on the derived occlusion.

33. The method of claim 32 further comprising: communicating digital information to the office of the orthodontic practitioner relating to the custom orthodontic appliance.

34. The method of claim 30 wherein: the deriving of the occlusion is carried out with a computer interacting with a user on a computer interface.

35. The method of claim 30 wherein: the digital information includes scanned three-dimensional data that includes the shapes of the teeth of the orthodontic patient, and the deriving of the occlusion includes defining relative positions of the teeth of the patient from the shapes from the three-dimensional data.

36. The method of claim 30 wherein: the digital information includes prescription data relating to the treatment of the orthodontic patient, and the deriving of the occlusion is in accordance with the prescription data.

37. A method of processing digital data for use in facilitating the orthodontic treatment of a patient comprising: scanning three-dimensional surfaces that have the shapes of a plurality of the teeth of a patient and generating data thereof; from the generated data, producing separate digital representations of

the shapes of each of a plurality of individual teeth of the patient.

38. The method of claim 37 wherein: the producing of the separate digital representations from the generated data includes the operator-interactive selection on a computer display of landmark parameters of individual teeth.

39. The method of claim 37 wherein: the producing of the separate digital representations from the generated data includes representing each of the plurality of teeth by a two-dimensional contour.

40. The method of claim 37 wherein: the producing of the separate digital representations from the generated data includes separating an image of the plurality of teeth into individual data-sets each representing an individual tooth.

41. The method of claim 37 further comprising: manipulating the separate digital representations of the generated data in a computer to rearrange the shapes of the individual teeth into desired relative positions.

42. The method of claim 37 further comprising: manipulating the separate digital representations of the generated data in a computer to rearrange the shapes of the individual teeth into desired relative positions; and designing geometry that defines custom orthodontic appliance surfaces based on the manipulated separate digital representations of the generated data.

43. The method of claim 37 further comprising: manipulating the separate digital representations of the generated data in a computer to rearrange the shapes of individual teeth in relation to scanned

skeletal data of the patient in desired relative positions.

44. The method of claim 37 further comprising: manipulating the separate digital representations of the generated data in a computer to rearrange the shapes of the individual teeth in relation to scanned data of the jaw of the patient in desired relative positions.

45. A method of processing digital data for use in facilitating the orthodontic treatment of a patient comprising: scanning the shapes of the teeth of a patient directly from the mouth of the patient and generating data thereof; grouping the generated data into separate digital representations of the shapes of each of a plurality of individual teeth.

46. A method of processing digital data for use in facilitating the orthodontic treatment of a patient comprising: configuring a local computer at the situs of an orthodontic practitioner for the entry of data relating to treatment for an orthodontic patient; and enabling the local computer to communicate entered data from the practitioner to a remote computer at a location remote from the situs of the practitioner configured for deriving custom geometry of an appliance for carrying out treatment of the patient in response to data entered by the practitioner at the local computer.

47. The method of claim 46 further comprising: providing the remote computer with operator-interactive software that is operative to design a custom orthodontic appliance at least in part in accordance with data entered by the practitioner on the local computer.

48. The method of claim 46 further comprising: providing the remote computer with operator-interactive software that is operative to design a custom orthodontic appliance in part in accordance with data entered by the practitioner and in part in accordance with algorithms programmed therein.

49. The method of claim 46 further comprising: providing the remote computer with operator-interactive software that is operative to calculate desired positions of the patient's teeth at least in part in response to data entered by the practitioner.

50. The method of claim 46 further comprising: providing the remote computer with operator-interactive software that is operative to calculate desired positions of the patient's teeth in part in response to data entered by the practitioner and in part in accordance with algorithms programmed therein.

51. The method of claim 46 further comprising: providing the remote computer with operator-interactive software that is operative to calculate desired positions of the patient's teeth in pa t in response to data entered by the practitioner, in part by data entered by an operator at the location remote from the practitioner, and in part in accordance with algorithms programmed therein.

52. The method of claim 46 further comprising: providing the remote computer with operator-interactive software that is operative to design a custom orthodontic appliance in part in response to data entered by an operator at the location remote from the situs of the practitioner.

53. The method of claim 46 further comprising: transferring data from the local computer to the re-

mote computer and operating the remote computer to derive geometry of a custom orthodontic appliance.

54. A method of providing digital data for use in facilitating the custom orthodontic treatment of a patient comprising: transmitting a model of the teeth of a patient to be treated at an orthodontic practitioner's facility to a facility remote therefrom having a computer thereat configured for digitally defining therewith positions to which to move the patient's teeth by orthodontic treatment of the patient; and facilitating treatment of the patient by the orthodontic practitioner to move the patient's teeth to positions digitally defined with the computer from tooth shape information derived from the model.

55. The method of claim 54 wherein the model is a digital model.

56. The method of claim 54 wherein the model is a physical model.

57. The method of claim 54 wherein the model is a digital model made by scanning shapes of the patient's teeth at the orthodontic practitioners facility.

58. The method of claim 54 wherein the model is a physical model made by forming an impression of the shapes of the patient's teeth at the orthodontic practitioners facility.

59. The method of claim 54 further comprising: digitally defining the positions to which to move the patient's teeth by arranging on the computer at the remote facility individual tooth shape data derived from the model to generate a three-dimensional representation of the positions of the patient's teeth in accordance with a prescription.

60. The method of claim 54 further comprising: digitally defining the positions to which to move the patient's teeth by arranging on the computer at the remote facility individual tooth shape data derived from the model to generate a three dimensional representation of the positions of the patient's teeth; and generating data of three-dimensional tooth-shape geometry for a custom orthodontic appliance to move the teeth of the patient to said positions.

61. The method of claim 54 further comprising: digitally defining the positions to which to move the patient's teeth by arranging individual tooth shape data derived from the model to generate a three-dimensional representation of the positions of the patient's teeth; generating data of three-dimensional tooth-shape geometry for a custom orthodontic appliance to move the teeth of the patient to said positions; and substantially automatically manufacturing the appliance having said geometry in accordance with the three-dimensional tooth shape geometry.

62. The method of claim 54 wherein the facilitating of the treatment of the patient includes providing an orthodontic appliance configured to move the teeth of the patient to the positions digitally defined with the computer at the remote facility.

63. The method of claim 54 wherein the facilitating of the treatment of the patient includes communicating instructions for treating the patient by moving the patient's teeth to positions digitally defined with the use of the computer at the remote facility.

64. The method of claim 54 further comprising: transmitting a prescription for the orthodontic treatment of the patient to the computer at the remote

facility; the facilitating of the treatment of the patient including facilitating treatment for moving the teeth of the patient to tooth positions digitally defined with the computer at the remote facility in accordance with the prescription.

65. The method of claim 54 wherein the facilitating of the treatment of the patient includes facilitating treatment for moving the teeth of the patient to tooth positions digitally defined with the use of the computer at the remote facility at least in part by interaction of an operator with the computer.

66. The method of claim 54 wherein the facilitating of the treatment of the patient includes providing data for the fabrication of an orthodontic appliance for use in moving the teeth of the patient to the digitally defined positions.

67. The method of claim 54 wherein the facilitating of the treatment of the patient includes facilitating treatment for moving the teeth of the patient to tooth positions digitally calculated by the computer at the remote facility at least in part in accordance with a predetermined computer program.

68. The method of claim 54 wherein the facilitating of the treatment of the patient includes facilitating treatment for moving the teeth of the patient to tooth positions digitally determined with the computer at the remote facility at least in part in accordance with a calculated dental archform.

69. A computer-implemented method for use in generating digital models of a patient's teeth, the method comprising: receiving initial data that contains a 3D representation of a plurality of the patient's teeth; identifying multiple groups of data, each group containing a plurality of points from the

initial data that separately digitally represent the shape of one of the teeth.

70. A method for defining an occlusion for upper and lower teeth of a patient, comprising: from three-dimensional data that contains a 3D representation of a plurality of the teeth of a patient, defining separate data of the surfaces of each of a plurality of different teeth of the patient; generating a computer representation of the upper and lower teeth of the patient that includes the separate data of surfaces of a plurality of the teeth of the patient; and determining with a computer an occlusion from the computer representation of the upper and lower teeth of the patient using one or more occlusion criteria of relationships between three-dimensional surfaces of different teeth.

71. The method of claim 70 wherein at least one of the criteria is selected from the group consisting essentially of: a relationship between cusps and ridges of molars, tooth crown angulation, lower jaw archform, cuspid rise, tooth contact point alignment, and an occlusal plane.

72. The method of claim 70 further comprising: identifying one or more landmarks among each of the separate data associated with the respective teeth; and determining the occlusion based on a relative arrangement of the identified landmarks of different teeth.

73. The method of claim 72 wherein at least one of the landmarks is identified substantially automatically by the computer.

74. The method of claim 72 wherein at least one of the landmarks is selected by a user interacting with a computer.

75. The method of claim 70 wherein the occlusion is an ideal arrangement of teeth.

76. The method of claim 70 wherein the computer representation is derived from a physical model of the patient's teeth.

77. The method of claim 70 further comprising: generating a digital model of the patient's teeth; and adjusting tooth positions in the model by following a prescription.

78. The method of claim 77 wherein the model is specified by one or more archforms.

79. The method of claim 77 wherein the model is customized to the patient's teeth.

reference is not to the pre-treatment occlusion, but rather to the desired finish positions of the teeth. Accordingly, the claim must be interpreted as requiring that a computer automatically derive the desired finish positions of the teeth, as distinct from the process used by Align.

Claim 46 refers to "deriving custom geometry of an appliance for carrying out treatment of the patient . . . ." A367. This "hook" is "deriving" and thus claim 46 is not infringed for the same reasons as claim 23.

Claim 54 refers to "a computer thereat configured for digitally defining therewith positions to which to move the patient's teeth . . . ." *Id.* "Configured for digitally defining" is the hook that links to automatic as opposed to skilled operator determinations of finish treatment positions for the patient's teeth.

Claim 70 refers to "defining an occlusion" and to "determining with a computer an occlusion . . . ." A368. This claim, for the same reasons as stated for claim 30, requires automatic determination by a computer of finish tooth positions such that Align's process, which relies on a skilled operator to make these determinations, is necessarily outside of its bounds.

b) Claims That On Their Face Do Not Require The Calculation Of Finish Tooth Positions

There are three independent claims of the '444 Patent, claims 37, 45 and 69, that on their face stop short of any aspect of the essence of the invention, either automatic calculation of the finish tooth positions, or automatic design, or automatic fabrication.

Align does not believe that such claims should properly have issued, and if construed without the limitation of computer determination of finish tooth positions (which Ormco used to distinguish the invention from Lemchen and other prior art), Align believes that the claims are necessarily invalid.[9] Atypically, neither claim 45 nor 69 has any dependent claims. Claim 37 has depending from it claims 38-44. Of these, claims 41-44 address rearranging the digital representations of the teeth in a computer to desired positions, A367, and this "rearranging" hooks these dependent claims into the limitation that the "rearranging" be done automatically in the computer, without skilled operator decision making to determine the finish positions.

Accordingly, even assuming that the Court accepts Ormco's view of the law (which Align does not agree is correct), the only claims that could survive this appeal are claims 37-40, 45 and 69 of the '444 Patent. Therefore, at the least, summary judgment of non-infringement should thus be affirmed as to the '432, '243, and '861 Patents, and as to all but claims 37-40, 45 and 69 of the '444 Patent.

* * * *

[9] Align is not proposing that the Court address the invalidity of these claims in the present appeal. Should the appeal revive these claims, Align will address their invalidity on remand.

APPENDIX G

* * * *

> Thus, this case is unlike *Gentry Gallery, in* which this court's determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element—the "control means"—as "the only possible location" and that variations were "outside the stated purpose of the invention." *Gentry Gallery,* 134 F.3d at 1479. *Gentry Gallery,* then, considers the situation where the patent's disclosure makes crystal clear that a particular *(i.e.,* narrow) understanding of a claim term is an "essential element of [the inventor's] invention." *Id.*

Here, the issue is not the meaning of a particular word, but rather that Ormco made it perfectly clear in the specification and in the cited file histories that *the very nature of its invention* was for automatic computer determination of the finish positions of teeth and automatic design of the appropriate wire and bracket appliance, as opposed to depending on determinations made by an orthodontist or skilled operator. Ormco should not be permitted to avoid summary judgment by focusing the Court's attention on principles of claim construction not here at issue.

The relevant authority cited by Align leaves no doubt that Ormco's claims are limited, and that no claim can be read to encompass that which was disclaimed. For example, in *Alloc, Inc. v. Int'l Trade Comm'n,* 342 F.3d 1361 (Fed. Cir. 2003), a case cited by Align in its Motion and ignored by Ormco in its Opposition, the issue was whether the limitation of

"play" should be read into claims concerning a flooring system, even though the claims did not recite this limitation. In concluding that the limitation of "play" must be read into the claims, the Federal Circuit stated:

> In so concluding, this court recognizes that it must interpret the claims in light of the specification, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *(en banc), aff'd* 517 U.S. 370 (1996), yet avoid impermissibly importing limitations from the specification. *Comark Communications v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). That balance turns on how the specification characterizes the claimed invention. *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1305 (Fed. Cir. 2003). In this respect, this court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment. For example, it is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. *Teleflex, Inc. v. Ficosa N.*
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(1986). Where, as here, the non-moving party will bear the burden of proof at trial, the moving party's burden is discharged when it shows that there is an absence of evidence to support the non-moving party's case. *Id.* at 325. The non-moving party must then meet its burden of showing that there is a genuine issue for trial. In so doing, it "may not rest upon the mere allegations or denials of [that] party's pleadings, but . . . must set forth specific facts . . . ." Fed. R. Civ. P. 56(e). The non-moving party must accordingly "identify with reasonable particularity the evidence that precludes summary judgment." *Keenan v. Allan,* 91 F.3d 1275, 1279 (9th Cir. 1996). If the nonmoving party fails to make this showing, after all justifiable inferences are drawn in its favor, the moving party is entitled to summary judgment as a matter of law. *Celotex,* 477 U.S. at 323.

2. Legal Principles of Claim Interpretation

Given Ormco's repeated representations about the nature of its invention, this motion should not require any detailed claim interpretation.[7] Each claim asserted against Align necessarily reflects and includes the fundamental nature of the invention—a

[7] Because Ormco's claims cannot cover subject matter outside the boundaries of Ormco's stated inventions, the claims need not be individually discussed in this non-infringement motion. Indeed, the large number of individual claims asserted by Ormco effectively precludes any such discussion within the confines of the page limitations. It is sufficient for non-infringement that Align's process and product fall outside the broadest boundary of Ormco's invention and therefore the broadest boundary of its claims.

computer which alone determines where the teeth are to be moved and designs an appliance in conformity. To the extent that Ormco asserts otherwise, any such interpretation would necessarily lead to a finding of invalidity based on the prior art and the lack of support in the specification. Nevertheless, Align will briefly review the basic principles of claims construction as they may apply to this motion.

The fundamental principles of claim interpretation were set forth in *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd* 517 U.S. 370

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